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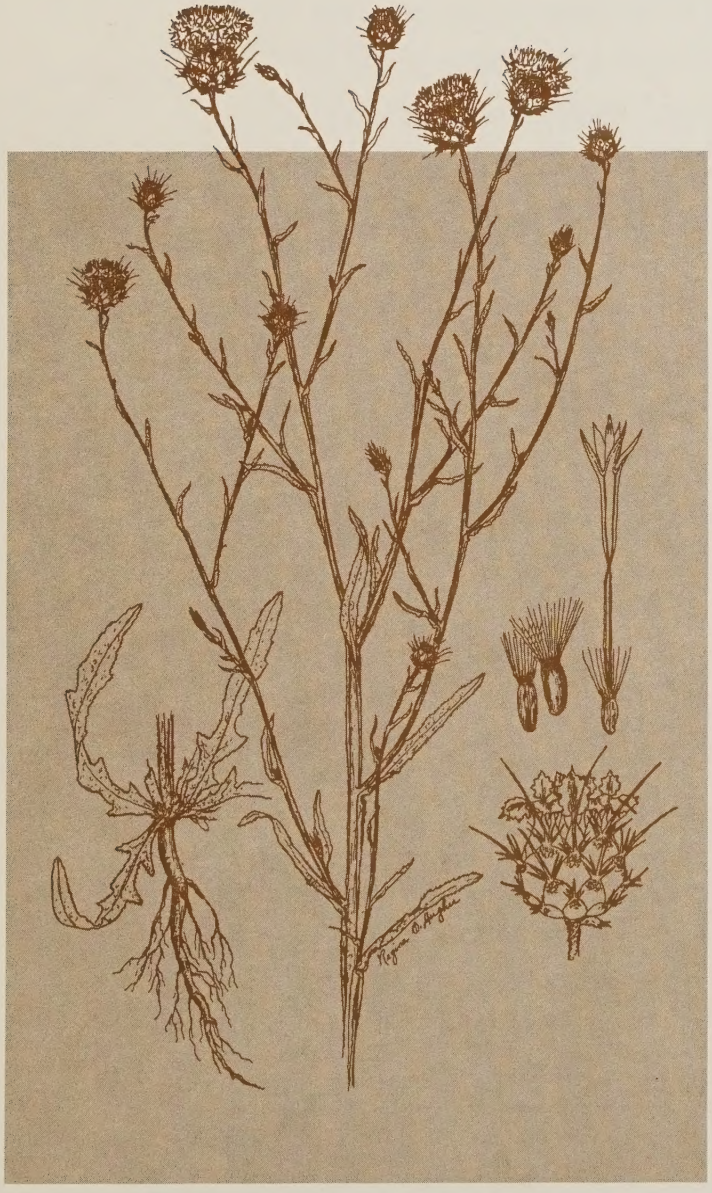
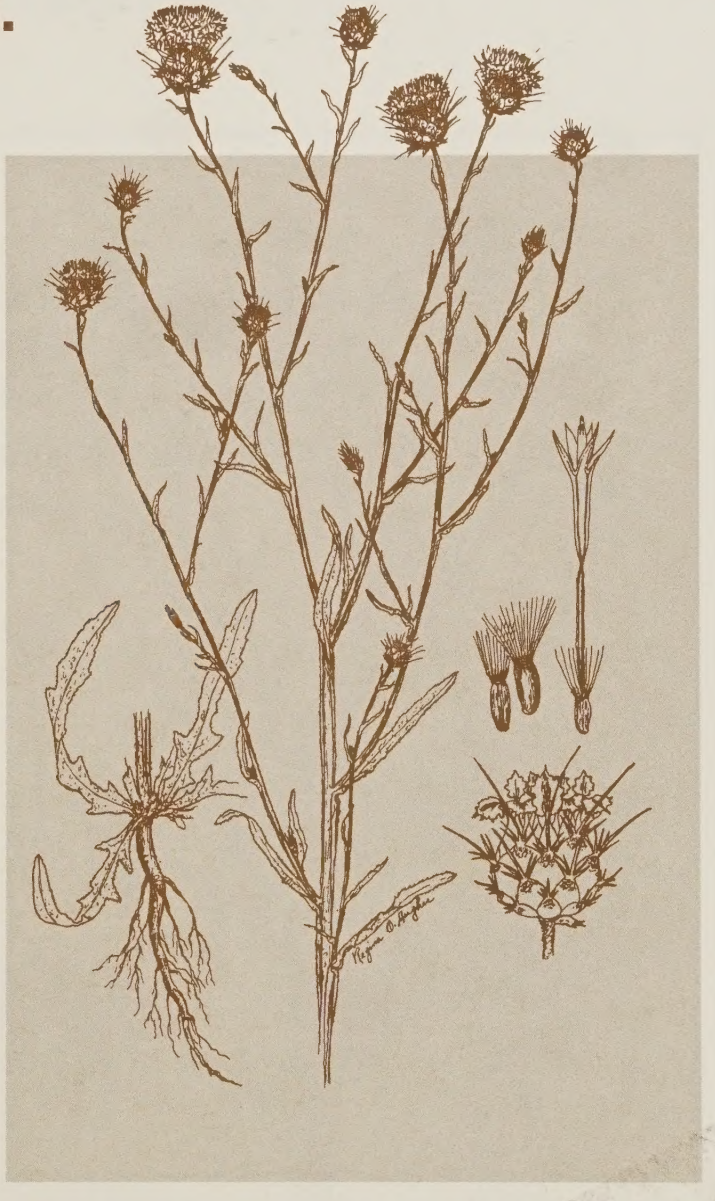
June 1997

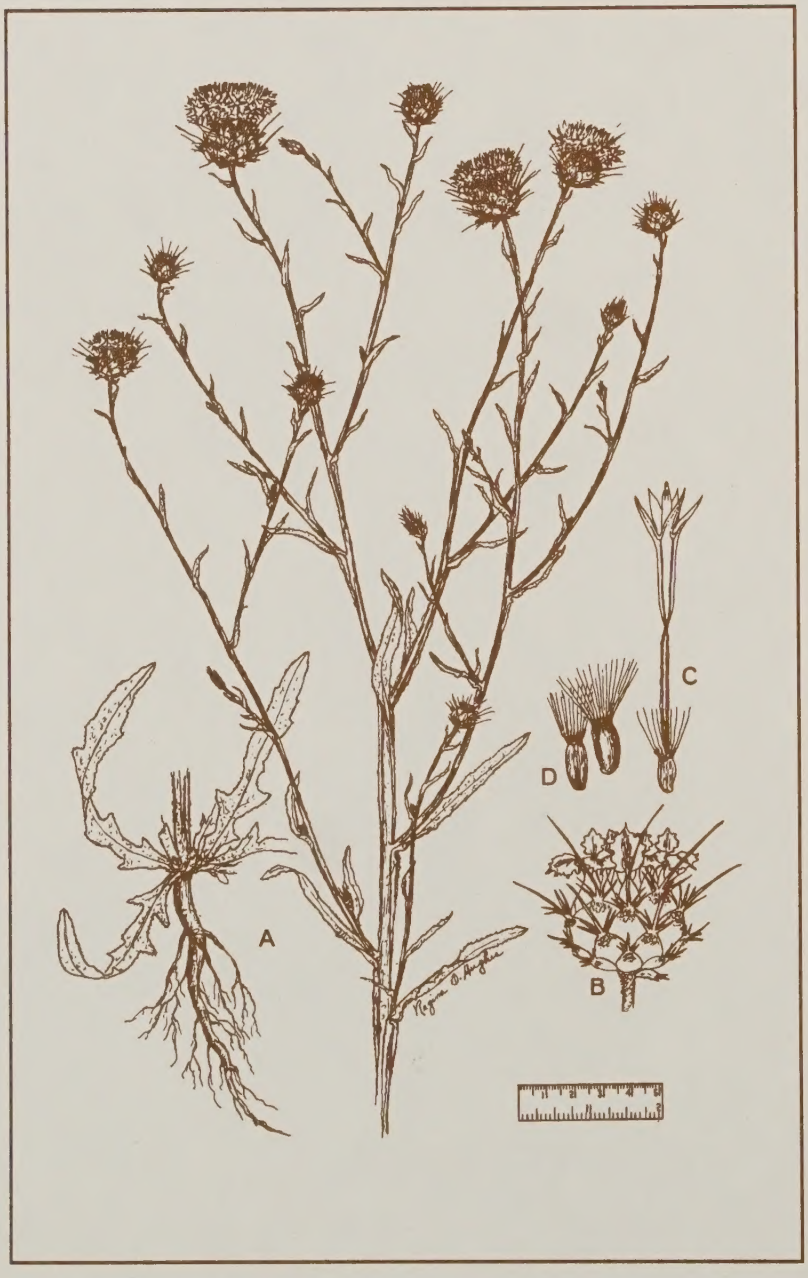
Proceedings of the Invitational Workshop on USDA Activities in Biological Control

Riverdale, Maryland, and Washington, D.C.





October 8 — 11, 1996



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Centaurea solstitialis L. Yellow starthistle.

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United States
Department of
Agriculture

**Agricultural
Research
Service**

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R.I. Carruthers and
J.K. Petroff, Editors

In cooperation with USDA/Agricultural Research Service, USDA/Animal and Plant Health Inspection Service, USDA/Cooperative State Research, Education and Extension Service, USDA/Forest Service, and U.S. Environmental Protection Agency

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While supplies last, single copies of this publication may be obtained at no cost from Raymond Carruthers, NPL, U.S. Department of Agriculture, Agricultural Research Service, Biological Control, BARC-West, Bldg. 005, Room 220, Beltsville, MD 20705.

Copies of this publication may be purchased from the National Technical Information Service, 5285 Port Royal Road, Springfield, VA 22161; (703) 487–4650.

Acknowledgments

Workshop and Steering Committee Co-Chairs: Dr. Raymond I. Carruthers, USDA/ Agricultural Research Service, and Dr. Sally L. McCammon, USDA/Animal and Plant Health Inspection Service. The Steering Committee members were: Ernest S. Delfosse, USDA–APHIS–NBCI; Allan Bullard, USDA/Forest Service; Robert Bridges, USDA/ Forest Service; and Sally Rockey, USDA/Cooperative State Research, Education and Extension Service. Special assistance was provided to the Committee by Stan Barras, USDA/Forest Service.

The *White Paper* providing background summaries and information for the workshop was prepared by the Steering Committee co-chairs, as well as: E. Delfosse, USDA–APHIS–NBCI; H. Browning, USDA–CSREES; A. Bullard, USDA–Forest Service; D. Herron, USDA–APHIS; S. Rockey, USDA–CSREES; and L. Wendel, USDA–APHIS.

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EXECUTIVE SUMMARY

At the request of Deputy Secretary of Agriculture Richard Rominger, a USDA inter-agency workshop was held on October 8-11, 1996, to provide guidance to the Department on coordination, regulation and accountability for the program area of biological control. Approximately 80 individuals from four USDA Agencies (Animal and Plant Health Inspection Service [APHIS], Agricultural Research Service [ARS], Cooperative State Research, Education & Extension Service [CSREES], and Forest Service), and certain representatives and partners from State Departments of Agriculture and Land Grant Universities participated in the workshop and were responsible for developing the information in the attached report.

The workshop was held to meet the following objectives: 1) To identify roles and responsibilities of USDA in the research, development, regulation, and implementation of biological control for the effective management of pests; 2) To recommend a way to coordinate work within and among USDA agencies to facilitate the use of biological control for the effective management of pests; 3) To make recommendations for a system that will increase accountability in USDA from regulations and research through delivery of biological control programs; and 4) To consolidate key ideas from the workshop into a form that can be used by USDA to develop biological control with a minimum of economic and environmental risk.

The findings of this group substantiate findings published by the Congressional Office of Technology Assessment in late 1995 and the National Academy of Sciences in early 1996; the following recommendations strongly reiterate statements made in those reports.

Consensus was reached by participants on all recommendations.

Workshop participants agreed that USDA needs to increase coordination of its biological control activities, significantly improve internal regulatory processes, and establish a documentable process of Agency accountability with respect to biological control research and action programs. A systematic approach for the selection, investigation, regulation, and implementation of biological control programs was seen as necessary for coordination. Identified areas for coordination in the Department included those for priority-setting in both research and action programs, field implementation and assessment, regulation and implementing procedures, technology transfer, and funding for grants and fund solicitation. Linkage across Federal Departments also needs increased coordination.

The group recommended that a Departmental-level "Center" be established to aid in inter-agency coordination of biological control activities and to provide guidance and oversight on regulatory matters within USDA and between other Departments and non-USDA Agencies. Such a Center would interface with the existing IPM Subcommittee, but needs to be operational and functional with dedicated staff positions appointed primarily from existing Agency positions. It was suggested that the Center be coordinated by a Director who would answer to the Deputy Secretary's Office as does the current IPM Coordinator. The Directorship could rotate among key Agencies involved in biological control programs. Additional Agency representatives, with appropriate authority to affect internal Agency activities, could be appointed to an oversight board that would also include influential customer representatives. This board would provide policy, program, and other guidance to the USDA through the proposed Center. USDA supports both the National Pesticide Impact Assessment and IR-4 programs in a somewhat similar manner.

In the area of regulations, the group recommended that USDA address the goals of protection, ensuring confidence in biological control regulation, and facilitation of the navigation of Federal and State regulatory requirements, and reassess the processes that are currently used to regulate beneficial organisms such as biological control agents and pollinators. These organisms are currently regulated under the Federal Plant Pest Act which many participants felt was not well-suited or appropriate for regulating beneficial organisms. The group felt that a regulatory system that focused on and dealt with the variety of organisms used for biological control was needed. Many of the workshop participants agreed that a new process needed to be designed as a "Facilitative Regulatory System" that encapsulates the customer-defined issues summarized in the National Biological Control Institute-facilitated "Strawman."

Embodied in the "Strawman" document and other cited publications are the elements that the group felt new regulations must contain: 1) consistency between regulatory requirements and the actual risk to non-target organisms and the environment; 2) assessment of benefits associated with any action, not just potential risks; 3) processes and assessments that are science-based and not founded on ungrounded speculation; 4) processes that are streamlined and efficient; 5) processes that are predictable, consistent, and avoid ad hoc decision-making; and 6) "one-stop shopping" for regulatory compliance to every degree possible within USDA authority. At the very minimum a one-stop shopping information system needs to be developed to guide USDA Agencies and customers through complex regulatory processes including the National Environmental Policy Act and the Endangered Species Act. The group also recommended that enabling legislation be pursued either through a separate Biological Control Act, the Research Title of the Farm Bill, or the APHIS Consolidated Statutes. The group strongly felt, however, that no matter which tack is taken, new laws, regulations, and implementing procedures must be enabling and must work to speed the introduction and use of safe and effective biological control agents.

To address accountability, the workshop participants felt that obtainable measures needed to be set and evaluated. These measures should assure that planning, investigation, and implementation of biological control programs occur across agency lines. The group recommended the use of a Government Performance and Results Act-based customer service plan and a model to better develop and deliver biological control efforts in a systematic manner across Agency lines. It was felt that a customer-driven process should be used to set goals, objectives, and specific program outcomes which could be accounted for at both national and local levels. Such a process would help to allocate resources, assess completion of project components, and provide feedback on projects from inception to completion through a Customer Advisory Board. Specifically, the group felt that the Customer Advisory Board would represent a very positive step in achieving input and providing customer accountability. The group strongly advised USDA to incorporate such an approach into any Departmental-level coordinating program or Center that might be developed.

In the summary session of the workshop, the participants outlined their needs to the USDA Administration, as well as their expectations, as follows:

- Ensure USDA commitment to follow through with workshop recommendations;
- Establish a USDA Biological Control Center and assign FTEs and funds to the Center to enable its operation;
- Provide authority (from each Agency and the Department) to the Center; and
- Empower a multi-Agency team to develop program specifics and implement the plan.

Within 90 days of this final report the workshop participants expect that the USDA will:

- Develop a plan to form the operational and functional Biological Control Center at the Departmental level;
- Have Deputy Secretary and Agency Administrators review and endorse the recommendations of this group; and
- Begin implementation and operation of all possible components of this reinvention, and support its continued operation.

GLOSSARY OF ACRONYMS

ANPR - Advance Notice of Proposed Rulemaking. An ANPR is published by a federal agency in the *Federal Register*. Its purpose is to solicit views on proposed changes in the law before the wording is finalized.
APHIS - Animal and Plant Health Inspection Service, a branch of the USDA.
ARS - Agricultural Research Service, a branch of the USDA.
BBT - Biologically based technology.
BLM - Bureau of Land Management, a branch of the USDI.
CDC - Centers for Disease Control.
CSREES - Cooperative State Research, Education and Extension Service; a branch of the USDA.
DoD - U.S. Department of Defense.
DoI - U.S. Department of the Interior; also USDI.
EA - Environmental Assessment. A short report describing the effects on the environment of an action such as introducing a foreign organism. As of 1995, APHIS requires that an EA be written for every proposed introduction of non-indigenous organisms. Sometimes APHIS will require the composition of a more detailed EIS (*see below*).
EIS - Environmental Impact Statement. A very detailed report describing the effects of an action on the environment.
EPA - U.S. Environmental Protection Agency.
ESA - Endangered Species Act.
ESCOP - Experiment Station Committee on Organization and Policy. A CSREES subcommittee that sets broad national guidelines for the vision and mission of State Agricultural Experiment Stations.
FACA - Federal Advisory Committee Act. In part, FACA outlines who can sit on a federal advisory committee and the implications for different kinds of representation.
FDA - U.S. Food and Drug Administration.
FHP - Forest Health Protection, an arm of the Forest Service.
FIDR - Forest Insect and Disease Research, an arm of the Forest Service.
FICMNEW - Federal Interagency Committee on the Management of Noxious and Exotic Weeds.
FIFRA - Federal Insecticide, Fungicide, and Rodenticide Act (1972).
FONSI - Finding of No Significant Impact. APHIS requires a FONSI for a foreign organism to be released into the United States.
FPPA - Federal Plant Pest Act (1957).
FS - Forest Service, a branch of the USDA.
FWS - Fish and Wildlife Service, a branch of the USDI.
GPRA - Government Performance and Results Act.
IBC^3 - Interagency Biological Control Coordinating Committee.
IIBC - The International Institute of Biological Control, a division of the Centre for Agriculture and Biosciences International, based in England. IIBC conducts foreign explorations and research for potential biocontrol agents.
IOBC - The International Organization for Biological Control.
IPM - Integrated Pest Management, a method of managing pests by combining different control techniques.
IR-4 - Interregional Research Project No. 4, a program to track pesticide use in minor crops.

MOU - Memorandum of Understanding; a formal document signed by representatives of two or more agencies that agree to work together in a specific way on an issue.
NAPIAP - National Agricultural Pesticide Impact Assessment Program.
NAPPO - North American Plant Pest Organization.
NBCI - The National Biological Control Institute, an APHIS program established in 1991 "to promote, facilitate, and provide leadership for biological control."
NEPA - National Environmental Policy Act (1970).
NPS - National Park Service, a branch of the USDI.
NSF - National Science Foundation.
OPRA - Organism Permitting and Risk Analysis; a process employed by APHIS.
OTA - Office of Technology Assessment. A Congressional office dedicated to in-depth reporting on issues assigned to it by Congress. OTA funding was discontinued in 1995. The OTA report *Biologically Based Technologies for Pest Control* was published in September 1995.
R & D - Research and development.
SARE - Sustainable Agriculture and Research Education, a USDA grant program.
SOP - Standard Operating Procedure.
TAG - The Technical Advisory Group for Biological Control Agents of Weeds (TAGBCAW). TAG reviews petitions for the introduction of non-indigenous organisms and recommends to APHIS whether to allow or deny the petitions. TAG consists of representatives from at least 10 federal agencies.
T&E - Threatened and endangered, as in species.
USDA - U.S. Department of Agriculture, which includes the Agricultural Research Service, Animal and Plant Health Inspection Service, the Forest Service, and the Cooperative State Research, Education and Extension Service.
USDA-APHIS-PPQ - The Plant and Pest Quarantine arm of APHIS.
USDA-APHIS-PPQ-BATS - The Biological Assessment and Taxonomic Support arm of APHIS; one of APHIS' regulatory bodies.
USDI - U.S. Department of the Interior, which includes the Bureau of Land Management, National Park Service, Bureau of Indian Affairs, Fish & Wildlife Service, and the Bureau of Reclamation.

WORKSHOP SYNOPSIS

Overview

On July 11, 1996, Deputy Secretary Rominger convened a meeting to acquire perspectives of USDA Agencies on an Advanced Notice of Proposed Rulemaking (ANPR) being developed by the Animal and Plant Health Inspection Service (APHIS). The ANPR was being submitted to help define new regulations and guidelines for nonindigenous organisms, including biological control agents. Customer and Agency concerns about the need for appropriate policies and a holistic approach to biological control research, implementation, regulation, and accountability led to the formation of a steering committee co-chaired by the Agricultural Research Service (ARS) (Raymond Carruthers) and APHIS (Sally McCammon) with input from the Deputy Secretary's Office (Larry Elworth). In addition, the Cooperative State Research, Education & Extension Service (CSREES), the Forest Service (FS) and the APHIS-National Biological Control Institute (NBCI) were represented on the steering committee. The charge to the committee was to determine what was required to better coordinate USDA biological control activities and to determine the characteristics of appropriate regulations, with the goal of enhancing accountability for and delivery of safe and effective biological control technologies for use in IPM programs.

The steering committee in cooperation with Larry Elworth determined that a workshop of USDA biological control experts was needed to make recommendations to the Deputy Secretary and various Agency Administrators on future needs for USDA biological control activities. As stated in a summary letter to Larry Elworth on August 15, 1996, "The purpose of the proposed workshop is to gain consensus on a Team USDA action plan to facilitate biological control program coordination and the development of regulations for delivery of safe and effective biological control programs."

Significant reviews of these subjects had been completed by the National Academy of Sciences and the Congressional Office of Technology Assessment within the past year. Many other groups had made similar written comments over the past decade; thus, the steering committee developed a *White Paper* (Appendix 1) summarizing key documents that were important as background for the workshop. Following review by the steering committee, this *White Paper* was sent to all invited participants as background information for the meeting that was held in Riverdale, MD, and Washington, DC, October 8-11, 1996.

Approximately 80 individuals (Appendix 2) from four USDA Agencies (APHIS, ARS, CSREES and FS), as well as certain representatives from the Environmental Protection Agency (EPA), State Departments of Agriculture, and Land Grant Universities met and discussed critical issues on biological control coordination, regulation and accountability. This report provides a summary of the findings and recommendations made to the Deputy Secretary's Office.

Overall Perceptions of the Workshop Attendees

The participants of the workshop unanimously agreed that increased coordination of activities and improved regulations are essential to make USDA biological control programs more efficient and to effectively incorporate them into the Department's Integrated Pest Management (IPM) Initiative. As a key component of this effort, the group felt that Agency-level accountability needed to be increased for future programs to help guarantee that all groups live up to Departmental and customer expectations. Workshop participants felt that

increased coordination at the Department level was required because:

- Current USDA biological control activities are fragmented within and between USDA and State agencies.
- USDA activities in biological control are less effective than they could or should be.
- The regulatory process has been unstable and inconsistent for years and has not met the needs of many internal USDA groups nor our external customers.
- Many groups are spending unreasonable amounts of time on regulatory issues and still are not in compliance with the National Environmental Policy Act (NEPA), the Endangered Species Act (ESA), the Lacey Act, etc.
- Many customers have asked for regulatory improvements which either have not been made, are coming too slowly, or if enacted, were not adequate.
- Many proposed solutions to both regulatory oversight and coordination of research and action programs have not been appropriate and have not been in balance with actual environmental risk or programmatic need.

Overall, the group concluded that the current organizational structure of the Department's biological control program within and between Agencies is inefficient, lacking in programmatic continuity and leadership, many times misfocused, and often falling short in the area of adequate implementation. Coordination of biological control programs across Agencies has not occurred either through actions conducted by individual Agencies or through the Departmental IPM Subcommittee. It was strongly felt that coordination of USDA biological control activities are in severe need of "Reinvention Through Modernization." The interagency group attending the week-long workshop contributed to the reinvention through full participation in support of realistic Team USDA solutions to these issues.

Improved regulations addressing the needs of beneficial organisms such as biological control agents and pollinators, and potentially a new biological control law, were identified by the group as key elements that must be urgently addressed by USDA. Such regulations need to be developed, implemented, and applied in a supportive, facilitative manner rather than as restrictive bureaucratic hurdles. Such a system would require a holistic approach to dealing with beneficial biological control agents, not the permitting process that is currently administered through the Federal Plant Pest Act (FPPA) with ad hoc decisions.

It was agreed that the biological control community (including commercial producers) need a facilitated system that can provide "one-stop shopping" for as many regulatory issues as possible. Currently, a number of regulations have to be addressed through an uncoordinated process that must meet the requirements of the FPPA, National Evironmental Policy Act (NEPA), Endangered Species Act (ESA), Lacey Act, Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA), etc. A detailed discussion of regulatory issues and reinvention needs will follow in a separate section; however, the group expressed a strong sense that any regulatory system that is developed needs to make major improvements in the process for approval for field release of beneficial microbial agents, particularly important pathogens of weeds and insect pests. These groups of beneficial organisms have been almost completely blocked from introduction into the United States over the past decade, yet are commonly used biological control agents throughout the world. This places the United States at a tremendous disadvantage in terms of international competitiveness and environmental protection.

Improved Departmental-level coordination of research and action programs for biological control was felt to be essential by all participants. Currently, inter-agency coordination of biological control programs is nearly lacking within the Department. To respond to this void, the group felt that a biological control coordinating body needs to be developed and should function somewhat like the Departmental IPM Subcommittee. However, any coordinating body should be operational and have associated staff contributed by the involved Agencies. The roles and responsibilities of the Department's biological control programs, including selection of targets, foreign exploration, quarantine evaluation, approval of exotic agents, and the field introduction of these materials, requires different functions for biological control programs than the IPM Subcommittee can address. Thus the group strongly recommended that a separate operational group be formed to assist the Department with planning biological control policies, developing a research and implementation philosophy, and coordinating operational activities across Agencies. Although a Biological Control Committee of this type would have different needs and responsibilities than the Department's IPM Subcommittee, the two groups must work closely together. Independent of the structure of such a

coordinating group, the outcome of the reinvention needs to provide an overall systematic approach for developing, regulating, and implementing biological control, and interfacing biological control technologies within the Department's IPM programs. In doing so, the Department's actions must ensure that accountability is built into the plan to measure effectiveness with the goal of continually improving the system.

The group also felt that activities of the coordinating body need to center on traditional biological control which includes biological control augmentation, conservation, introduction, and microbial control technologies. However, the program must continue to modernize through facilitating programs that will accommodate new biologically based technologies (BBTs) as they are developed, and then work directly with the Department's IPM Subcommittee to assist others in developing or using new BBTs (e.g., genetically engineered products) in IPM programs.

Summary of Recommendations for Coordination of Programs

Workshop representatives from several states (Departments of Agriculture and universities) formally proposed that USDA establish a Center at the Department level to promote, facilitate and provide leadership across all Agencies conducting biological control. They stressed that this is needed to ensure that an overall systematic approach is developed within USDA to select, investigate, regulate and implement appropriate programs. The term "Center" was proposed by the group and is used throughout this summary; however, the concept and not the title is the important aspect of their proposal. The intention is that individuals from multiple Agencies need to be formally assigned to this effort and housed together to meet the associated set of responsibilities specifically assigned to a USDA Biological Control Center. Such a structure differs from that of the USDA IPM Subcommittee, which only convenes occasionally with members that normally fulfill other diverse duties within their respective Agencies.

Consensus was reached by participants on the following recommendations.

The Center must use a facilitation model of operation, not dictatorial command-and-control methods. The National Biological Control Institute (NBCI) was highlighted as an example of how such a Center should operate. However, a USDA Biological Control Center would differ from NBCI because it would require representation from all USDA Agencies and would maintain an inter-agency staff that works together as a group to meet Team USDA objectives. Such a staff would not require a significant number of new positions, but could be composed primarily of existing personnel from affiliated USDA Agencies.

It was suggested that the Center be coordinated by a Director who would answer to the Deputy Secretary's Office as does the existing IPM Coordinator. However, the Director's appointment could be from any Agency and may rotate. Action items for the Center would be solicited primarily from customers, scientists, and Agency representatives who would serve as advisory group members to the proposed Center.

The workshop participants felt that the personnel in the Center could help prioritize targets, plan programs, document introduction activities, and pull together biological control programs across groups in different USDA Mission Areas; would help biological control practitioners (scientists, commercial producers, importers, etc.) attain one-stop shopping (or at least assistance) on regulatory procedures; would promote biological control through education of the general public, producers, environmental groups, etc.; and could help champion biological control at local, state, national and international levels.

The group felt strongly that such a Biological Control Center must have Department-level status, some full-time staff, and active representation from all Agencies - similar to pesticide-oriented programs like National Agricultural Pesticide Impact Assessment Program (NAPIAP) and Interregional Research Project No. 4 (IR-4). The representatives should have adequate authority to influence Agency programs, and USDA customers must have mechanisms for program input, assessment of impact, and therefore, program accountability. Elements identified by the group that specifically need enhanced coordination across Agencies include, but are not limited to:

- -Program priority-setting across Agencies, including management activities of research and action programs;
- -Priorities for specific research and action programs within Agencies;
- -Funding areas for grant programs;
- -Field implementation efforts and assessment technologies;

-Regulations and implementing procedures developed and used specifically for biological control;
-Technology transfer efforts;
-Solicitation of funds across Agencies; and
-Enhancement of overall program accountability.

The group also determined that USDA needs to develop and foster enhanced linkages within and between other Departments and Agencies within the Federal government, including the EPA, the Department of Interior (FWS, BLM, NPS, etc.), and others as appropriate for biological control program development and regulation. These groups could be invited to participate in the Center through liaison representatives.

Summary of Recommendations for Regulations

A new approach to the regulation of biological control agents and other beneficial organisms such as insect pollinators was recommended. Leadership for the regulation of biological control organisms is needed to develop an appropriate regulatory system. Authority and accountability for this system should be within APHIS or at a higher level within USDA. This system should address not only permitting under existing authorities, particularly the FPPA, but compliance under NEPA, for the implementation of projects and programs, as well as permitting. Confusion exists over the implementation of NEPA in the permitting process and in programmatic activities. As stated previously, USDA regulations of the introduction of beneficial organisms are now processed by APHIS under the FPPA, which was developed to exclude unwanted pests rather than permit the introduction of beneficial organisms. Recent changes in APHIS operations now require that NEPA assessments for biological control agents (except weed control agents) be conducted by the developing Agency rather than APHIS. These changes require that APHIS, ARS, CSREES, FS and other Agencies/Departments involved in biological control each must develop and implement their own NEPA procedures for the assessment and introduction of beneficial natural enemies, which was felt to be wasteful and duplicative. The EPA (through FIFRA) and the Department of Interior (through the ESA and the Lacey Act) are also involved in the regulation of exotic beneficial organisms and should be contacted early in the process of assessing the feasibility of introducing beneficial organisms. These non-USDA regulatory groups have expressed the need for USDA to consolidate permit-requesting activities rather than have each Agency contact them independently.

The workshop participants pointed out that due to the confusing nature of the existing regulatory system, the lack of a clear roadmap to compliance requirements, and no centralized assistance in meeting these requirements, many USDA Agencies and external customers have not been in compliance with existing laws and regulations. Since lack of compliance to federal law is not acceptable, and the use of beneficial biological control agents has the potential to be highly beneficial for agriculture and the environment, the group strongly recommended the development of a centralized program to assist Agencies in maneuvering through unclear regulations and procedures. This centralized program could be a responsibility of the proposed USDA Biological Control Center mentioned previously.

In addition, the group suggested that a new "Facilitative Regulatory System" be developed to improve the evaluation and permitting process for beneficial organisms. The workshop participants strongly stated that the USDA biological control regulatory process should include an assessment of, and implementation of, where appropriate, the ten (10) critical elements outlined in the NBCI "Strawman" document. Although some modifications may be required in the customer-derived and NBCI-summarized points documented in the Strawman, the primary elements are: 1) Modifications to the FPPA; 2) Notification for importation and interstate movement of precedented and unprecedented organisms; 3) Approval of quarantine and containment facilities; 4) Notification for release of precedented organisms; 5) Commercial biological control agents; 6) Release into the environment of unprecedented organisms; 7) Exclusions from regulatory oversight; 8) Conflict resolution procedures; 9) Enabling legislation; and 10) Customer service.

The question of regulatory authority over beneficial agents needs to be legally explored; some groups point out that since many of these agents are not plant-feeders, APHIS has no regulatory authority in this area under the FPPA. In fact, this is the primary reason that APHIS is no longer conducting NEPA assessments for biological control agents that do not directly affect plants. The group recommended that enabling biological

control legislation be considered as it is in some other countries, or that expansion of other regulatory authority be considered. Possibilities such as a separate Biological Control Act, the Research Title of the Farm Bill, or the APHIS Consolidated Statutes should be considered. The biotechnology regulatory system was also mentioned as a model. The group strongly felt, however, that no matter which approach is taken, new laws, regulations, and implementing procedures need to be enabling in nature and work to speed the introduction and use of safe and effective biological control agents for agriculture and forestry, and that one group should be responsible for all categories of agents.

The primary goals of new regulations and implementing procedures for biological control agents and other beneficial organisms would be to: 1) Protect U.S. agriculture, forests, human and animal health, and the environment/ecosystems, and to enhance trade; 2) Ensure the public and agricultural community's confidence in a regulatory system for biological control that fosters public support, facilitates programs, and helps overcome obstacles to research and commercialization; and 3) Facilitate timely implementation of biological control by satisfying legal requirements under various authorities of the law, including the Plant Quarantine Act, FPPA, Animal Quarantine Laws, NEPA, ESA, Lacey Act, and various state laws.

The group determined that an effective regulatory system should include the following attributes: 1) Consistency between regulatory requirements and the actual risk to non-target organisms and the environment; 2) Assessment of benefits - not just potential risks - associated with any action; 3) Processes and assessments that are science-based and not founded on ungrounded speculation; 4) Processes that are streamlined and efficient; 5) Processes that are predictable, consistent, and avoid ad hoc decision-making; and 6) "One-stop shopping" for regulatory compliance to every degree possible within USDA authority. At the very minimum, a "one-stop shopping" information system needs to be developed to guide USDA Agencies and customers through complex regulatory processes including NEPA and ESA.

Several additional points were highlighted by the group for consideration by the Department when assessing the need for new consolidated regulatory procedures. First, one of the major issues that continues to cause problems is unclear jurisdiction within and between Agencies/Departments in the area of biological control regulation. Clear coordination of regulatory goals and authority needs to be outlined within USDA. Only then can we work effectively across Departmental lines to establish new Memoranda of Understanding with other groups like EPA and the Fish and Wildlife Service of the Department of Interior. Such MOUs need to be developed and fostered to further facilitate USDA biological control programs. This is, again, an activity that can best be accomplished at the Department level. The workshop participants suggested that this could also be the responsibility of the proposed USDA Biological Control Center.

In summary, the workshop participants felt that a new regulatory system within USDA was necessary and that a central clearinghouse for biological control was needed at the Department level to help facilitate USDA permit requests as well as other biological control activities. A central clearinghouse would also work to bridge the current communication gaps between regulatory groups, within and between USDA and other groups, while providing oversight assistance in meeting all federal legal requirements in the area of biological control. Representatives from several State Departments of Agriculture were highly supportive of this approach and requested that specific coordination take place with the states, private biological control producers, and other customers/stakeholders during the process to facilitate feedback and improve customer service.

Accountability for Biological Control by USDA

The workshop participants felt that USDA Agencies need to work more effectively across Agencies to plan, investigate and implement effective biological control programs. USDA Agencies such as APHIS, ARS, CSREES, FS, etc., have overlapping mandates and responsibilities through the processes of research, regulation, implementation, evaluation, technology transfer, education, methods development, etc. Although some overlap of program areas and responsibilities is necessary and beneficial, the group agreed that Agency Administrators and their staffs need to develop more effective mechanisms to allow joint program planning and transitions as programs move across Agency lines. Specifically related to biological control program coordination, numerous points of interaction and interdependence were obvious to the group, yet they agreed that cross-agency planning often does

not get adequate attention. The specific areas that would benefit from joint planning include target identification, foreign exploration, agent evaluation, regulatory approval, introduction and establishment evaluations, and economic analysis of impact. Again, the group felt that a USDA Biological Control Center that answers to the Deputy Secretary's Office and is guided by outside advisors with input from customers, should be established to facilitate biological control programs and assess program effectiveness. This group should advise Agencies on the importance of specific projects, assess the response of the Agencies, keep customer groups and the Deputy Secretary's Office informed of project potential and progress, and thus provide direct program feedback and accountability.

The group felt that currently there is no uniform selection and development of projects across Agencies and that programs should be more systematically planned, developed and linked from initiation through implementation. Doing so would ensure that USDA will not spend large amounts of time and money on programs that never become fully realized or are blocked from success because of the lack of specific supporting information or technology that is available elsewhere in the Department. Departmental-level planning using a GPRA-based customer service plan and a program logic model would better develop and deliver programs in a systematic manner across all the involved agencies. It was felt that such an activity should be developed to set goals, objectives, and specific program outcomes that could be accounted for at national and local levels. Such a process would work to allocate resources appropriately, assess completion of project components, and provide feedback on projects from inception to completion.

To assure Departmental and Agency accountability, the group recommended that objective measures needed to be set and evaluated. These include both program-specific qualitative and quantitative factors identified by the workshop participants, and overall measures of program impact and success. Quantitative measures of the overall impact and success include: number of producers and land managers implementing biological control; increase in number of emerging biological control businesses; increase in non-USDA resources contributed to such programs; decrease in pesticide use; and increased agricultural profitability. More qualitative measures include: biological control being accepted as a significant pest control technology; public acceptance of biological control as a technology; advances in science; and healthier ecosystems where biological control has replaced less environmentally friendly technologies.

In summary, the workshop participants felt that USDA needed to improve system accountability in the area of IPM and biological control by including more customer input into both program planning and evaluation. Specifically, the group felt that the development of a Customer Advisory Board would represent a very positive step in achieving input and customer accountability and should be incorporated into any Departmental-level coordinating program.

The States' Perspective on USDA Biological Control Efforts

Representatives from State Departments of Agriculture and the Land Grant University system participated in the overall workshop and shared consensus with the other participants on the recommendations in this summary, but also met as a consolidated group to develop an outside perspective that could be shared with USDA Administrators.

The States felt that the most important concepts to focus on were the need to protect American agriculture and the environment from the ravages of noxious insects, weeds and diseases, and the need to accelerate the development and implementation of cost-effective, environmentally safe alternatives to chemical pesticides. The implementation of more biological control would bring about a positive economic gain for farmers and ranchers. As more and more chemical pesticides show up in groundwater or cause other problems, biological control as a pest control technology is becoming more desirable.

Because there is a current lack of coordination at the national level, and because there is a current lack of leadership across USDA agencies, and because there exists a fragmentation of responsibilities among several USDA agencies (and other Departments), and that these factors have resulted in confusion and delay in the implementation of biological control, the States recommend that the following be done:

What needs to be developed:

- A smooth process to implement biological control from inception of a project through release and monitoring.

- A facilitated regulatory process that is based on regulations that are streamlined, clearly written, sensible, and regulate in a manner that is consistent with risk.

- A coordinated approach to projects, which includes responsibility for planning, resource allocation, roles, time frames, and accountability.

How it could be done:

- By developing an overriding USDA biological control philosophy, policies that reflect that philosophy, and actions to implement it in a consistent, timely manner throughout the agency (and elsewhere as possible).

- By positioning a Coordinating Group at the Deputy Secretary level. To truly function as a champion of biological control from a cohesive national perspective, this group would facilitate, promote, and provide leadership for biological control policy, facilitate biological control activities throughout USDA, and act as liaison with other agencies, Universities, and the States. The state representatives felt that the National Biological Control Institute (NBCI) is a model that already functions much like a Coordinating Group could be envisioned. NBCI's scientists have accomplished a great deal with very limited resources. Fully implementing the role of the Coordinating Group would require at least the same level of staffing as in NBCI, plus additional staff from ARS, CSREES and FS. It was felt that the Secretary of Agriculture should establish and empower this Coordinating Group with the authority to accomplish its mission.

- By charging the writers of the regulations, including the current ANPR, to create a new regulation that incorporates the elements of the "Strawman" document, followed by implementing procedures that are clear and responsive to the needs of the customers while continuing to protect U.S. agriculture. A charge from the Secretary and oversight from the Coordinating Group is necessary to complete this task.

The states recommended that significant progress toward these goals be made by the rapid establishment of the Coordinating Group.

Outcomes of Improving Coordination, Regulations and Accountability of USDA Biological Control Programs

The workshop participants were both hopeful and realistic in their views of what could be accomplished through improving USDA efforts in the area of biological control. The group divided these outcomes into short- and long-term benefits. The short-term benefits related primarily to operational improvements in USDA's biological control activities within and between Agencies, while the long-term outcomes related more to the societal and environmental impacts that improved biological control programs would provide over several years if programs were accelerated and implemented within the Department's IPM Initiative.

The short-term outcomes of implementing the group's recommendations include: a systematic and efficient biological control system from identifying targets and agents, through regulation, to implementation, release and evaluation; a greater role of biological control and other biologically based technologies in IPM programs for weeds, insects, nematodes and plant diseases currently not managed, providing additional alternatives for pest control in a variety of agricultural production systems and natural environments; implementable alternatives to pesticides under regulatory review; assurance that biological control is credible and safe; acceleration of the safe use of biological control organisms into the field; implementation of a greater number of and more effective biological control agents for controlling pests in integrated systems; increases in stakeholder satisfaction and confidence in biological control and biological control operational efforts in the USDA (many stakeholders view our current IPM and biological control activities as uncoordinated and many times misdirected); assurance of compliance with NEPA and other Federal laws; scientists conducting science instead of being bogged down with bureaucratic regulatory procedures; and assurance of proper stewardship of Federal resources, including the taxpayers' dollars and the

management of natural resources and Federal lands.

The long-term outcomes identified by the group include: improved human and environmental health; increased economic returns and economic benefits for producers and better returns on U.S. investments; increased public confidence in food safety; and reduction in economic and environmental losses from pests.

Needs from the USDA Administration

Workshop participants agreed that there is a need for a strong commitment from the USDA Administration if biological control is to be strengthened. In particular, the following points were considered critical:

- Ensure USDA commitment to follow through with recommendations and proposed solutions;
- Establish a USDA Biological Control Center and assign FTEs and funds to the Center to enable its operation;
- Provide authority (from each Agency and the Department) to the Center; and
- Empower a multi-Agency team to move forward in developing program specifics and implementing the plan.

Expectations of Workshop Participants

Within 90 days of this final report the workshop participants expect that USDA will:

- Develop a plan to form the operational and functional Biological Control Center at the Departmental level.
- Have the Deputy Secretary and Agency Administrators review and endorse these recommendations.
- Begin implementation and operation of all possible components of this reinvention process and support its continued operation and success.

Summary Oral Report

A summary oral report was made by the workshop reporting team (R. Carruthers [USDA-ARS], S. McCammon [USDA-APHIS], L. Bezark [California Department of Food and Agriculture], and S. Rockey [USDA-CSREES]) to USDA Agency Administrators at the end of the workshop.

The presentation was made at 10 a.m. Friday, Oct. 11, 1996, at the U.S. Department of Agriculture Jamie L. Whitten Federal Building in Washington, D.C. Senior agency personnel attending were: Floyd Horn, ARS Administrator; Ed Knipling, ARS Deputy Administrator; Dick Parry, Director, ARS Office of Technology Transfer; Terry Medley, APHIS Administrator; Ann Bartuska, Staff Director, Forest Health and Protection, Forest Service; Barbra Webber, Associate Deputy Chief for Research, Forest Service; Al Elder, Deputy Administrator, APHIS Plant Protection and Quarantine; and A.J. Dye, Assistant to the Administrator, CSREES.

A transcript of the discussion that followed this oral report can be found on page 45 of these *Proceedings*.

Invitational Workshop on USDA Activities in Biological Control

Riverdale, Maryland, and Washington, D.C. October 8-11, 1996

WORKSHOP ORGANIZATION

To meet the challenge of Deputy Secretary of Agriculture Richard Rominger, workshop participants integrated information and recommendations from presentations, group discussions, and facilitated breakout sessions into this final report addressing the critical issues of biological control coordination, regulation and accountability. Participants prepared for this workshop by reviewing a background *White Paper* (Appendix 1), the USDA-APHIS Advance Notice of Proposed Rulemaking (Appendix 4), and other important documents such as the Office of Technology Assessment's 1995 report titled *Biologically Based Technologies for Pest Control* and the National Academy of Sciences' 1996 report titled *Ecologically Based Pest Management.*

The first three days of the workshop were divided into sessions that addressed three issues: Coordination, Regulation and Accountability. (A complete Workshop Agenda is recorded in Appendix 3.) On the fourth and final day, the results were assembled and a formal summary report was presented orally to Agency Administrators (or their representatives) and other U.S. Department of Agriculture personnel. A written Workshop Synopsis (pages v-xvi) provides a summary of the participants' findings and recommendations to the Deputy Secretary of Agriculture. As a group, the workshop participants believe that these recommendations directly address Larry Elworth's Charge (page 4), especially in providing guidance to the Department as it deals with a number of difficult issues to improve biological control coordination and regulations. As stated by Mr. Elworth, and agreed upon by the workshop participants, we do not want or expect this activity to be "just another bureaucratic exercise." Therefore, the group addressed several critical issues head-on and now expects Department and Agency Administrators to do the same.

Sessions I-III

In the first three sections of these *Proceedings* (Session I: Biological Control Coordination in the USDA, page 5; Session II: Biological Control Regulation in the USDA, page 17; and Session III: Biological Control Accountability in the USDA, page 36), plenary presentations are summarized in the form of abstracts (submitted by the speakers) or transcriptions. During the workshop, each presentation was followed by a question-and-answer period. After listening to each session of speakers, the group discussed the overall issues. Highlights of these discussions have been summarized in bullet form throughout the report.

Following the general discussions, the group was refocused by invited speakers who addressed issues in the *White Paper* that were critical to each session, and then briefly discussed these issues with the group prior to dividing the participants into facilitated breakout groups for detailed consideration of potential solutions. Following several hours of deliberations by the breakout groups, group facilitators met and combined the groups' recorded information (see Appendix 5 for a complete list of breakout group results) into a synopsis that was subsequently reviewed in plenary session where final recommendations were developed and refined. The pertinent synopsis is recorded in these *Proceedings* at the end of each session (pages 16, 34, and 37).

Session IV

In Session IV (page 39) of the workshop, participants developed a formal draft plan for the Coordination, Regulation and Accountability of Biological Control in the USDA. The group worked as a whole to consolidate the findings from Sessions I-III into a comprehensive summary for the Deputy Secretary's Office. Although the bulk of the time in this session was used to clarify items from the previous days' discussions, new observations were made and are summarized in bullet form (page 40).

Session V

The final summary report was outlined by the group as a whole in Session V (page 41), and then formalized overnight by a reporting team. The reporters rehearsed their presentations with the workshop participants on the last morning of the conference and final adjustments were made to both summary oral statements and accompanying visual aids to accurately represent the participants' conclusions. An oral presentation of the workshop's final results was made to the Administrators (or their representatives) of APHIS, ARS, CSREES, FS and other key members of the U.S. Department of Agriculture. An open discussion of the issues with the USDA representatives concluded the workshop.

WELCOME

Raymond Carruthers, USDA-ARS, Beltsville, MD; and *Sally McCammon*, USDA-APHIS, Washington, D.C.

Planning for this workshop began with a meeting in USDA Deputy Secretary Richard Rominger's office in July 1996. Because the actions of any one agency in this field affect every other agency, Mr. Rominger wanted to bring together all the agencies that dealt with biological control of pests to discuss coordinating biological control processes and regulations.

Our first step was to document the state of biological control coordination, regulation, and accountability as it exists today. This documentation can be found in the *White Paper* distributed to all workshop participants. (See Appendix 1.) We hope that this workshop will take us to the next step - a cohesive plan for USDA biological control in the future. With input from our cooperators, we need to develop this plan as "Team USDA." There is a lot to do, and today's workshop is the beginning of the process.

Introductions

Participants introduced themselves and offered potential workshop results that would point to success. Their responses included:

* Establishment of a Departmentwide mechanism to coordinate and focus biological control efforts. Better cooperation among agencies to maximize resources. To have the right people at the right Departmental level coordinate/regulate biological control.
* A consensus on biological control regulations that are streamlined and coherent, particularly including guidelines for the introduction of non-indigenous and non-traditional organisms.
* More rapid development of biological control technologies.
* An approach to biological control that incorporates a field perspective and that includes stakeholders in the development of biological control technologies.
* More Congressional support for biological control research.
* Modernization of infrastructure (and regulations) for efficient delivery of biological control technologies to customers.
* Establishment of a mechanism to promote, facilitate, and provide leadership in biological control.
* Better coordination of biological control efforts among states.
* Proper balance of domestic and overseas biological control efforts.
* Development of comprehensive project plans that include technology transfer and monitoring.
* Understanding of the role of biological control in support of agriculture.
* A consensus on biological control research.
* Resolution of conflicts of interest within the biological control community.
* An improved, streamlined biological control development process that makes a smooth transition from research to permitting to implementation.
* Establishment of a national biological control program, from exploration to delivery to the field.
* Fish & Wildlife Service involvement with respect to threatened and endangered (T&E) species.
* Action taken on results of this workshop.

CHARGE TO PARTICIPANTS

Larry Elworth, Special Assistant for Pesticide Policy, U.S. Department of Agriculture, Washington, D.C. 20250

TRANSCRIPTION: Biological control is an important issue for a lot of reasons. Biological control has a lot of promise, but there's a wide spectrum of beliefs about its effectiveness. Diverse opinions result in lots of expectations and, therefore, some controversy. Our current institutions weren't designed for facilitating biological control, nor were our laws. Our scientific disciplines don't necessarily make cross-disciplinary work (which is necessary for biological control) easy. Our technology transfer is strained trying to bring this technology to farmers. Our pest management systems aren't set up to simply replace pesticides with biological controls. Despite (or because of) these challenges, USDA needs to find a way to deal with this technology. Our working hypothesis is that biological control does have promise, it's a promise we can capitalize on, and it's a promise we need to bring out to the field. At a minimum, the federal government should not put up roadblocks to this technology.

My charge to you is to:

* Identify the roles and responsibilities of USDA in the research, development, regulation and implementation of biological control;
* Recommend a way to coordinate work within and among USDA agencies;
* Make recommendations that increase the accountability of the USDA; and,
* Consolidate ideas from this workshop into a form that can be used by the USDA to develop biological control systems.

Many of us have been through these exercises before. We need to build on the work we've done and not reinvent the wheel.

There is an institutional commitment within USDA today to coordinate this work among our agencies and use that as the first step to coordinating well with people at the state level, at universities, and in the private sector.

We want to fully involve people outside USDA to help us figure out the most appropriate thing to do. USDA's overall goal is to make sure our regulations are appropriate. We want your help to streamline the process.

We also want to make sure that any further regulatory steps we take facilitate biological control, but at the same time provide a regulatory underpinning for what we do. An appropriate but credible regulatory system is the best way to assure the public of the safety of this technology. Keep that in mind as you look at the regulations - they have a value to us, as well as to the private sector.

We also need to focus our research and methods on the important problems that people face in the field. The only way people will adopt new practices is if the practices address real problems. If we want funding for programs, we must demonstrate that the programs help solve problems in the real world.

As we decrease our reliance on pesticides nationally, it's also important for us to look for opportunities where biological control can fill the gap. There's a significant expectation in the USDA today that we can develop and deliver the tools to do this.

I and the Deputy Secretary don't want this to be just another bureaucratic exercise - that is not a suitable outcome. I urge you not to skirt any difficult issues. If you come up with a general consensus document that doesn't address the difficult issues, I'm afraid you folks have wasted your time and we'll have to come back a year from now to revisit this topic. So look at the hard issues, thrash them out, make good recommendations to us. If there's work that needs to be done at the Secretary's level, let us know. We look forward to seeing what you come up with.

SESSION I: Biological Control Coordination in USDA

PANEL PRESENTATIONS ON ROLES, RESPONSIBILITIES, AND PRIMARY NEEDS

APHIS Roles, Responsibilities and Primary Needs in Biological Control

Al Elder, Deputy Administrator, USDA-APHIS-PPQ, 302-E ADMB, Washington, D.C. 20250

WRITTEN ABSTRACT: The specific mission of "biological control programs" within USDA, Animal and Plant Health Inspection Service (APHIS), Plant Protection and Quarantine (PPQ), is to implement biological control technologies in a cooperative effort with other Federal and State Agencies to control pests of economic and environmental importance. Biological control programs are conducted in close cooperation with State Departments of Agriculture, USDA Agricultural Research Service, Cooperative State Extension and Education Service, Forest Service, international institutions, other countries, universities and industry. The PPQ Plant Protection Laboratory Centers provide the basis for the control of agricultural and environmental pests including insects, mites and weeds through the mass production and release of native and/or exotic natural enemies for the establishment and distribution of natural enemies, or using the direct control of a pest through augmentative biological control technologies or as part of an integrated pest management program. Two Centers have approved quarantine facilities in order to receive, test and/or screen exotic natural enemies and pest organisms from abroad. PPQ is presently implementing biological programs against nine arthropod pests and eight weed pests.

Coordination is critical to the successful implementation of each project. In an effort to address pest problems in a coordinated manner, PPQ recently has worked with its cooperators to develop biological control action plans at the regional level in order to assure that its programs are aligned with needs and priorities at the State level. Through surveys, pests have been prioritized by the States in order that we may focus and leverage resources more effectively and target the need for funds in priority areas. The North East Regional action plan calls for Regional Biological Control Committees; mechanisms to assure technology transfer and communication; and linkage into the network of pest control activities that exist operationally such as the Cooperative Agricultural Pest Survey (CAPS). Thirty-eight pests were identified and prioritized in 1996. APHIS currently has workplans in place for 10 pests in the Northeast region. A similar approach is being taken in the Western Region to identify the 10 top rangeland weeds that the Western states designate as important. Although these coordination efforts have just been started and, as with all new approaches, have had some problems, we feel that this type of approach, working with the customers, is the way of the future.

Through its Plant Health Center, PPQ and APHIS hope to link the scientific community and state-of-the-art science and technology into eradication and control programs and risk assessment. The National Biological Control Institute (NBCI) has just recently been moved into PPQ to assure closer links to program activities through association with the Plant Health Center. NBCI has been particularly effective in facilitating and promoting biological control. For instance, NBCI is addressing the need for providing increased and focused funds for biological control in several ways such as the small grants program that was established in 1990, in collaboration with other Federal and State agencies. Five NBCI Fellows have been named to date through the NBCI Postdoctoral Fellowships in Systematics. In addition, NBCI has facilitated the exchange of biological control information in a variety of other areas, including: initiation of the development of the National Biological Control Information Center (a combination of NBCI and ARS Biological Control Documentation Center information activities); establishment of a bulletin board system and the first World Wide Web Internet Home Page for biological control; and institution of a Customer Advisory Group. NBCI brings experience and capabilities that

will help PPQ link more effectively with the scientific community on pressing pest needs.

In support of the APHIS Philosophy for Biological Control, APHIS is committed to the process of developing regulations that will facilitate the release of certain safe biological control agents, while maintaining adequate protection for American agriculture and the environment. We firmly believe that our regulatory procedures and policies have been major contributing factors to the safety record of biological control for a good portion of the last 100 years. Oversight occurs under the mandate of the Federal Plant Pest Act, the purpose of which is to protect U.S. agriculture and the environment from depredation that could result from certain organisms if they were to be introduced and become established. As a result, there are obvious regulatory concerns and responsibilities for the importation and release of plant feeding or plant pathogenic organisms used in the biological control of certain weedy plant species. However, in a not so obvious way, APHIS regulatory responsibilities cover parasites, predators, pathogens, antagonists, and competitors used in the biological control of plant pests. APHIS continues to be committed to facilitating the safe and effective use of biological control organisms to suppress plant pests. In these cases, the emphasis is on assuring that no potential plant pest risk is presented in movement or release. APHIS has recently published an Advance Notice of Proposed Rulemaking (ANPR) in the Federal Register to receive input on this and other aspects of the regulations. Comments on this ANPR should be submitted by December 26, 1996.

Coordination to leverage resources and avoid duplication of effort and to tackle the most pressing problems is going to be a key to effective use of biological control. There are critical needs in biological control to be addressed at this meeting. Some of these needs include: 1) Cooperation amongst Federal Agencies to identify and prioritize biological control projects; 2) Provision of a transition process for programs ready to shift from research to implementation agencies; 3) Leveraging resources between Federal agencies, States, and the private sectors; 4) Developing systematic approaches to utilize biological control technologies for integrated pest management; 5) Leveraging money for research into the development of classical and augmentative biological control; 6) Utilizing scientific input for risk assessment effectively; 7) Developing an expeditious process to safely permit the release of exotic natural enemies; and, 8) Developing more effective communication between agencies for biological control programs.

Additional comments:

APHIS provides regulatory oversight of non-indigenous plant pests to protect U.S. agriculture. The criticial point is the definition of a "plant pest." The Advance Notice of Proposed Rulemaking (ANPR) addresses this issue. APHIS continues to be committed to the safe use of biological control, but we have concerns. Our regulatory procedures have contributed to the safety of this discipline. We'll continue to provide this necessary service. APHIS is committed to developing clear and appropriate guidance and regulations.

Coordination is the key to the effective use of biological control.

Biological Control Coordination: One State's Perspective

Cindie Fugere, North Dakota Department of Agriculture, 600 E. Boulevard, 6th Floor, Bismarck, ND 58505-0020

WRITTEN ABSTRACT: I am especially appreciative of people working in USDA agencies to improve the coordination, regulation and accountability for biological control technologies. The states need this increased commitment to produce successful biological control technologies, more than most people recognize.

Leafy spurge is an example of one of the many invasive weeds that continues to cause serious economic and biological impacts to local communities across the nation. It has advanced its range to 23 states, most of which do not recognize the danger this weed poses.

Leafy spurge infests nearly one million acres in North Dakota. It causes $24 million dollars in lost income to agricultural producers each year. The average annual net farm income in North Dakota is $27,000. This income is supposed to provide family living and make principal payments; therefore, it is understandable why farmers and ranchers cannot afford the risk of allowing leafy spurge to continue its advance. If the income lost to leafy spurge alone is multiplied to what it could generate in our local communities, it would be found that leafy spurge is robbing our economy of over $70 million each year.

In North Dakota, Federal funding, Federal programs and Federal people were combined with state resources in 1991 to begin implementing a large-scale biological control program for leafy spurge. In 1996, just five years later, farmers and ranchers received over 4.5 million insects through the North Dakota Biological Control Program. Producers are enthusiastic about learning this new technology, not because they want to learn to predict the life cycle of insects, but because it offers them renewed hope of restoring productivity to their land.

Farmers and ranchers have learned from experience they need additional tools to fight this weed because the recommended herbicides are too costly for large infestations.

The North Dakota Department of Agriculture, together with willing local and federal partners, worked to diversify a $4 million restricted-use herbicide spraying program into integrated management programs during the past five years. Nearly all the 53 county and seven city weed boards, as well as the the state and Federal land management agencies, are implementing appropriate integrated pest management technologies. These technologies include grazing systems and classical biological controls, in addition to herbicide spraying programs for leafy spurge.

Integrated pest management for leafy spurge has been a primary goal for our state. Biological control is an important new tool that has been added to the toolbox. The Federal government has been the primary source of our biological control technology.

What states need from the Federal government:

* Increased foreign exploration to find species that can decrease weed infestations.
* Federal research and development of pathogens.
* Federally funded mass-rearing research and implementation.
* A balanced number of quarantine facilities, maintained by the federal government and funded to function for the long term.
* Programmatic EIS documentation to assist researchers and federal land managers.
* Field implementation assistance for fledgling state partners who request it.
* Long-term monitoring to understand the successes and effects of biological controls.
* A commitment to participate in the "consortium concept," so partners know what to invest financially and what to expect from that investment.
* People who recognize that the WEEDS are the problem, not the regulations or the agencies.
* A commitment from people and agencies to put an end to the professional and scientific separateness that exists between the various disciplines (biological, chemical, cultural, etc.) that must be combined to ensure successful integrated pest management.

These problems require that we all work together, with USDA accepting the fundamental responsibility to produce this technology. We look forward to the additional tools the federal government will make available for the toolbox we use to fight the massive infestations of noxious weeds in the states.

Additional comments:

Each county in North Dakota has its own weed program. The total county weed program budget is about $2.2 million. That money, together with the $1.2 million allocated to weed programs by our state Department of Agriculture and $1 million from the Department of Transportation, in the past has been spent solely on restricted-use herbicides. Now it is spent on implementing integrated management systems, including grazing, biological control, etc. Our state weed program has $1.2 million, a two-

person staff, and runs a grant program which has been good for integrating management systems. Our Biological Control Coordinating Committee includes representatives from the state, the universities, ARS, and APHIS, and is trying to blend programs. Cooperation improves each year. We promise to do our best with the biological controls that you give us. More implementation is needed at the farmer/rancher level.

Biological Control Coordination: A State's Perspective

Tim Butler, Oregon Department of Agriculture, 635 Capitol St. NE, Salem, OR 97310-0110

WRITTEN ABSTRACT: USDA and other cooperators need to improve their approach to weed biological control as a set of comprehensive projects, integrated with other control technologies, which includes clearly defined goals and identifies participants and their responsibilities. Coordination between USDA and cooperators has been minimal, with no formal oversight and limited feedback. This has resulted in incomplete projects which have not targeted all available niches of several target weed species. Clearance and establishment of new agents has often been the primary goal of researchers, not control of targeted pest species. Because of the lack of an overall comprehensive effort, post-establishment monitoring and evaluation have received little attention as essential elements of biological control projects. Currently, many cooperators tend to view USDA primarily as a supplier of biological control agents.

Essential project planning includes: setting goals, timelines, mileposts, identifying resource requirements, and responsibilities. This approach has been applied in the case of purple loosestrife. The loosestrife project includes needed key elements: a clear definition of the problem (purpose and need), oversight and coordination, a working group and project leader, defined goals and predictions, distribution of guidelines for agent release and propagation, and plans for monitoring and evaluation of impacts. The loosestrife project demonstrates a total comprehensive project package.

USDA needs to strengthen project components such as technology transfer, monitoring, evaluation, and post-introduction management as part of each project plan to improve use of available resources and success of biological control.

Additional comments:

The Oregon Department of Agriculture has worked with biological control for more than 20 years. It is working on about 25 weed species.

The Department of the Interior must be included in biological control coordination. It oversees a large land base. It implements the Endangered Species Act which directly involves decisions on the importation of agents. We must bring all these folks into the loop.

Coordination improves opportunities. When we work together, we save time, resources, and money. We need to do a more efficient job on the ground.

Biological Control: A Forest Service Perspective on Roles, Responsibilities and Primary Needs

Allan Bullard, Director, USDA Forest Service, Forest Health Technology Enterprise Team-M, 180 Canfield St., Morgantown, WV 26505

WRITTEN ABSTRACT: The Forest Service mission is to achieve quality land management under the sustainable multiple-use management concept to meet the diverse needs of people. As a part of this mission, the Forest Service is responsible for protecting and managing the National Forests and Grasslands and for developing and providing scientific and technical knowledge aimed at improving our capability to protect, manage, and use forests and rangelands. Biological control of insects, diseases and weeds has been and is becoming

an increasingly important tool in our ability to meet our mission requirements.

Within the Forest Service, Forest Insect and Disease Research (FIDR) is focusing their efforts on insects and microorganisms that are pests, particularly exotic species. Their emphasis is on the development of classical biological control, using the natural predators and parasites of these pests to help manage or suppress them. As a part of these efforts, FIDR has extensive networks of foreign cooperators, works closely with colleagues in APHIS and ARS, and the FIDR unit at Hamden, CT, maintains the only Forest Service primary quarantine facility. In addition to classical biological control emphasis, FIDR has studies underway on the use of pheromones and behavioral chemicals as well as development of microbial pesticides to help control pests. Biotechnology is another area of research focus. It is being used to both develop more effective virus formulations (for example) and to develop trees that are resistant to insect and disease pests.

Forest Health Protection (FHP) is responsible for monitoring and evaluating pest conditions, providing land managers with technical assistance in this area, conducting methods improvement evaluations, and for management and suppression of pests within the Forest Service and on state and private lands through cooperation with state agencies. Beginning in 1993, biological control and biopesticide development and improvement within FHP was centered in a single unit, now known as the Forest Health Technology Enterprise Team in Morgantown, WV (FHTET-M). FHTET-M collaborates and cooperates with FIDR, APHIS, ARS, states, universities, international agencies and others to help develop, improve and carry out these activities on a broad range of pests, mainly non-indigenous pests, in U.S. forests. To help coordinate activities within the Forest Service, FIDR anbd FHP recently entered into a partnership program with each contributing $200,000 to be used to develop technology related to non-indigenous pest problems, including weeds.

Primary Forest Service needs in the area of biological control include a continued and increased level of cooperation and coordination with other USDA agencies responsible for biological control development and support, development of clear lines of responsibility governing biological control activities within the USDA, and clear, streamlined processes for import, quarantine, release and monitoring of biological control agents in this country.

Additional comments:

The Forest Service is responsible for 191 million acres of national lands. It is also responsible for helping state and local people protect and care for their forests, and for helping states implement biological control on their forest lands. The increased emphasis on biological control is driven, in part, by the decreased emphasis on traditional pesticides.

We're working on a number of pests, including gypsy moth (classical biological control, plus viral insectides), western spruce budworm, southern pine beetle. All the pests are non-indigenous species except one, so we must go overseas to find biological control agents.

From a Forest Service perspective, we want:

- *To increase the level of coordination among USDA agencies, and expand that coordination to other agencies;*
- *To have clear lines of responsibility and authority in the development and implementation of biological control programs - and make sure we all understand what the lines are;*
- *To streamline the process of importation, quarantine, release and monitoring of biological control agents;*
- *To make this an actual tool in the toolbox. Biological control will be one of the pillars of integrated pest management.*

Perspectives of the USDA-ARS National Program Staff

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TRANSCRIPTION: Coordination, regulation, and accountability are three essential elements to an effective program for biological control in the United States. To be successful, we need to reach beyond "Team USDA" and become "Team Biological Control" involving all the affected agencies, stakeholders, and elements of the private and public sectors.

Overview of ARS activities: ARS conducts a variety of research. It spends more than $100 million/year on biologically based technologies (BBTs) for pest control. Based on recent reports, ARS is expected to accelerate the development of these technologies. Traditional methods of biological control (conservation, augmentation, classical, and microbial biological control) represent about 50% of ARS research programs. BBT programs cover 275 research projects implemented by about 180 SYs. ARS maintains four overseas labs to identify, collect and evaluate biological control agents for importation. Many U.S.-based scientists also collect natural enemies overseas and send them to quarantine for further screening. ARS maintains six primary quarantines. Non-traditional technologies (pheromones, mating disruption, behavior-modifiers, genetically-modified organisms, etc.) are also under development by ARS scientists. Ray Carruthers is the ARS point person for biological control, but others on the National Program Staff also have responsibilities in this area.

ARS project development and implementation: The ARS National Program Staff looks at programs, puts together a budget for Congress, allocates funds directed by Congress, and evaluates programs. Once program objectives are established, programs are turned over to Research Leaders and Area Directors. The programs are implemented by Category 1 research scientists who write a project statement (3-5 yrs). The statements are reviewed externally and then modified to address any issues that might have arisen. Laboratories are also reviewed every 3-5 years. In all reviews we try to involve customers and stakeholders. Category 1 scientists are reviewed annually, and in addition have career reviews by a panel of peers every 3-5 years. We have a written guide used for program evaluation.

Where do we go from here? ARS would like to have a specific set of prioritized research needs that can be developed cooperatively. We want to come together and make sure we're all singing from the same song sheet. We need to develop a consistent process to accomplish this. This workshop is a good first step toward institutionalizing such a process. We want to get consistent information and requests and know what's expected of us. Conversely, ARS wants to more clearly articulate what technologies we have ready for implementation. Let us know where there are gaps in our research programs so we can provide you with the information you need to implement biological control. We want your input, and in the spirit of cooperation we'll tell you where we think you can help, too. It's not Team ARS or Team USDA. It's Team Biological Control - and we've got a problem to solve, so let's solve it.

Perspectives of USDA-CSREES

Sally Rockey, USDA-CSREES, 301 D St. SW, Rm. 328, AG2240, Washington, D.C. 20250

TRANSCRIPTION: Cooperative State Research Education and Extension Service (CSREES) is in the business of knowledge generation and dissemination through formal and informal education. Knowledge is the key to the effective use of biological control. It's a knowledge-intensive technology that's constantly changing.

Sometimes it appears that there's a "Valley of Death" between where research is performed and knowledge is implemented. However, with biological control we have a great opportunity for implementing the knowledge that is generated.

What is CSREES? "Cooperative" in our title implies partnership. We rely on the land grant university system and our other partners to

realize our mission. In Washington we provide the leadership and distribute funds to those who research the problems and implement the solutions.

We've been involved with biological control for many years. The university system provides our connection to the end users of the technologies. CSREES provides support through: formula funds (base funds) to universities for Extension activities; grant programs (some research, some competitive grants); National Research Initiative, a major agricultural research grants program; and the Pest Management Alternatives program, which is in its second year and which gives preferential treatment to those who propose alternatives to traditional, chemically based treatments.

We want to examine all portions of biological control, including pathogens and nematodes. We look at it as a complete biological control system. We want to assure that the research we support is relevent.

CSREES needs better coordination with USDA. We are able to mobilize the land grant system and use it to the benefit of biological control. We want to be sure that we generate sound knowledge for dissemination.

Roles, Responsibilities, and Needs for Biological Control Coordination in the USDA: A Land Grant University Perspective

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WRITTEN ABSTRACT:

BACKGROUND
Each state and territory has usually one Land Grant University (LGU) involved in agriculture programs. The responsibilities of LGU's include research, resident instruction, and extension. One aspect of the agricultural mission of LGU's, as supported by CSREES, that makes it unique compared with USDA agencies, is that the LGU's must address state problems, whereas USDA agencies such as APHIS, ARS, and FS are mandated to conduct larger regional and national programs. Individual LGU programs may be smaller in scope, but collectively are equally important to stakeholders.

Most, if not all, states have some biological control research in one or more of the pest disciplines; several hundred LGU scientists are involved nationwide. Research funding has come from a variety of sources; these include, but may not be limited to, the following:

* Hatch and McIntire-Stennis;
* NRI competitive grants, including the biological control program that has been very important in transitioning basic and applied funding needs;
* NSF, for more basic research to better understand biological control organisms;
* regionally-administered programs such as SARE, ACE, Tropical Agriculture (CBAG and PBAG), and regional IPM programs, which are very important because they fund adaptive research, but are limited and short-term;
* states, but the level of support for biological control varies substantially; and
* industry.

LGU's are also responsible for conducting outreach activities. This is primarily accomplished through the Cooperative Extension Service (CES). Most LGU's have one or more extension scientists conducting educational programs in the broad area of pest management. But few extension scientists have specific training or experience in biological control. Extension biological control programs were virtually non-existent 10 years ago, but are starting to be developed in some states. One important partner in CES are the counties. There are thousands of county and area-wide extension offices throughout the country. County agents and farm advisors are an important contact for farmers, but most county extension personnel have little or no exposure to biological control. The numbers of extension personnel, both state and county, are declining. Also, state extension faculty have assumed a larger role in adaptive research and resident instruction. Therefore, although there is more to teach to farmers, there is less time and fewer people to do it. This has obvious

consequences for the adoption of biological control.

COORDINATION AND COOPERATION

Among Universities

National LGU research directions in biological control are partially coordinated by the ESCOP Biological Control Working Group. At the regional level, several CSREES regional research projects are involved in biological control. Many of these committees have APHIS and ARS representation in addition to university scientists representing their individual states. The importance of these projects for purposes of coordination of regional biological control activities cannot be overemphasized.

There is no formal coordination of extension biological control programs at the national or regional level. There has been limited support for educational projects through various CSREES programs, such as IPM, NAPIAP, and IR-4. The Facilitation Grants program of the National Biological Control Institute (NBCI) has provided limited but highly important support of extension biological control programs. In the North Central States, a well coordinated and effective region-wide extension biological control program has developed as an outgrowth of the regional arthropod biological control research project (NCR-125).

Between Universities and USDA Agencies

There has been generally good cooperation between university scientists and ARS and FS colleagues, but this has varied greatly from state to state and project to project.

There are three primary areas of interaction between university scientists and APHIS: (1) biological control regulations, (2) Biological Control Operations, and (3) the National Biological Control Institute. Regarding regulatory issues, university biological control workers have generally had a positive collective experience when interacting with the permitting staff within BATS. However, there has been a lengthy history of problems regarding specific regulatory issues; these problems need to be resolved to accelerate the rate of development and implementation of new biological controls that involve the use of exotic natural enemies. University scientists have also had significant philosophical disagreements with the work conducted by Biological Control Operations (BCO; now within the PPQ Plant Health Labs), especially in the choices of target species and appropriate natural enemies. Also, state scientists have often not been consulted or even notified of BCO activities being proposed or conducted within their states. University scientists generally have a positive view of the National Biological Control Institute. Its staff has attempted to sort out the regulatory issues, it has facilitated communication within the biological control community, both within and outside of the USDA, and its facilitation and systematics grant programs have provided important sources of funding not available through other channels. A significant concern about NBCI is the constraints placed upon it by its location within APHIS-PPQ.

PRIMARY NEEDS

The Land Grant universities have the following needs in their relationships with USDA agencies regarding biological control matters.

* The continuation of CSREES sponsorship of regional biological control research projects is essential.
* A continuation of the biological control program within the National Research Initiative is a critical need in support of state and regional research.
* Extension Service should provide funding to allow each state to send one extension specialist to attend the appropriate regional CSREES biological control project meetings to foster greater cooperation among university research and extension workers throughout the development of regional or multi-state biological control programs.
* States should put greater emphasis on extension biological control programming. Because of declining extension resources, CSREES should target biological control as an area of focus for expanded extension programs.
* There is a need for greater access to funding university scientists wishing to conduct classical biological control (from foreign exploration, through quarantine, to release) on a state and regional basis. There should be increased opportunities from CSREES programs, as well as a facilitation of interaction with ARS scientists and overseas labs.
* USDA should evaluate the current status of quarantine labs nationwide and facilitate the development of a network of labs readily available to university

scientists. For example, there were no active quarantine facilities in the North Central states until Ohio State University recently opened a small facility; unfortunately the facility is inadequate to address the needs of the entire region. There are very few quarantine facilities for biological control of weeds nationally.

* There needs to be a satisfactory resolution of regulatory issues to enhance and accelerate research and implementation of biological control, while assuring environmental safety.
* A process should be established to facilitate communication with APHIS biological control programs so that university scientists are involved in projects from the earliest possible stage.
* A biological control coordinating structure within the USDA would greatly facilitate interaction and cooperation between USDA agencies and the Land Grant universities.

CONCLUSION

The Land Grant University system constitutes a major participant in the development and implementation of biological controls. In addition to regional and national activities, university scientists must address the more localized needs of their individual states, filling important needs not usually addressed by the larger regional and national programs of ARS, FS, and APHIS. University scientists welcome continued cooperation with our USDA colleagues, and appreciate the support of CSREES staff regarding biological control matters.

ACKNOWLEDGMENTS

R. Charudattan, University of Florida, T. Kring, University of Arkansas, and J. Obrycki, Iowa State University reviewed this manuscript and provided useful suggestions.

Additional comments:

At the Land Grant Universities we do research, instruction, and deal with problems at the state level. Most states have biological control research, but this varies tremendously from state to state. Land Grant Universities are major players in the biological control arena.

Regional integrated pest management (IPM) programs are important because they're applied, but funding is often limited and short-term, whereas biological control research requires long-term commitments to funding. Some state Departments of Agriculture are more active than others in directing biological control research to their universities, so it's not an even playing field when it comes to funding at universities.

Large-Group Discussion of Biological Control Coordination

• In New Jersey we're trying to promote more privatization, to make biological control a good business. • One of ARS' primary goals is to transfer technology into the private sector. Getting private sector companies interested in some biological control projects is very difficult. • How can USDA encourage private sector involvement? • There's a difference between self-propagating agents and augmentative biological control, as far as business is concerned. Self-propagating agents may not be a technology that can be transferred to the commercial sector.

• The main barrier to collaboration is agency-specific funding and competition for funding in the scientific environment. • How can we go across agencies to put together cohesive programs? • Even within the Forest Service, each of three units has specific funding. But this year our technology development program has put together funds for which regions apply. Each unit contributes to the pot, then works on parts of the pot within their purview.

• Regarding biological control of weed research in ARS, cuts in personnel and many retirements will mean the end of the program unless we pump this up. The destruction of the ARS lab in Bozeman, MT, shows a lack of cooperation. • The Montana ARS program will be moving to Sidney, MT, but it's not destroyed. It will continue to cooperate with Montana State University, North Dakota, and other states and agencies.

• The consortia idea has been very successful in some instances. We work closely with other entities, pool our money, cross international boundaries. • Many groups can be and are involved. In these days of shrinking budgets, we

have to think in terms of creative funding. There are some models we can look at (e.g., the Montana Department of Agriculture's Noxious Weed Trust Fund).

• There is more to biological control than just the agent-delivery system. Many things have to come together to make biological control an implementable technology.

• How do we link with stakeholders and growers and producers? • We need joint prioritization of resources.

• The USDA's IPM program could be a model of inter-agency coordination. • As far as the IPM Initiative, it's good for making policy decisions, etc., but we in biological control really need operational coordination to make the technology work. The IPM Initiative may not be the right model for us. • We need to shoot higher.

• Coordination implies being aware of each other's work, but also taking advantage of it by sharing research plots, etc. Collaboration implies co-labor, i.e., we define together what we want, then share publications, tech transfer activities, resources; we do everything together. Unless we all buy into this, we'll fall short of the goal. • The way to get cooperation is to provide a pot of money and require a cooperative effort to get the money. The impetus today is funding and publications. All the higher-level coordination in the world will have no effect unless it happens on the ground. • Australia has models for this sort of thing.

• APHIS is in the process of rule-making. How will these conference proceedings fit within the rule-making process? • This conference is the informal part - not part of the formal rule-making process. This conference will help APHIS form the overall process. • This conference is not a substitute for involvement in and comment on the ANPR.

• To further coordination, we need a discussion of the quarantine system across the agencies - identify needs and practical applications, get the politics out of it, and coordinate resources. • ARS held a workshop three years ago: Biological Control Quarantine: Needs and Procedures. We need to develop coordination at a higher level, a Department level. • The 1996 Farm Bill created an advisory committee to make recommendations on programs to advise USDA Secretary Glickman on government facilities needs. We need to get to know the people on the 15-person committee that provides general oversight, identifies the gaps, and provides a high level of coordination. • They are a new bunch of players in town: National Research Education and Economics Advisory Board, chaired by Dr. Victor Lechtenberg, Dean of Agriculture at Purdue. They just started meeting.

• We need to coordinate biological control in the field and in quarantine facilities. The barrier is funding. We need to develop priorities so we can collaborate better. • Our challenge will be to determine exactly what that enabling mechanism can look like. Should we start from grassroots and go up, or top down, or start at the regional level? We'll have to decide how it all might work.

Discussion of *White Paper* Recommendations for Coordination, Cooperation, and Facilitation of Biological Control in USDA

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TRANSCRIPTION: More than 20 reports produced over the past 10 years identified coordination of programs and funding as a key need in biological control efforts. Three program issues were highlighted:

* competitive (resulting in higher costs and risks)
* duplicative (several federal agencies involved in exactly the same activity)
* misdirected ("squirt and count" biological control is too often funded, rather than funding basic mechanisms and monitoring).

Attempts at federal coordination have been made:

* The ESCOP working group on biological control highlighted the need to "coordinate efforts toward a common goal."
* OTA said that NBCI was effective beyond the Beltway, but not involved in the IPM Initiative, which perpetuated

separation between biological control and IPM pest control disciplines.
* IBC[3] was never funded, so couldn't ever do much.

The report produced by the Office of Technology Assessment provided nine options to improve coordination. (*See White Paper*, Appendix 1.)

Summary questions: What is meant by coordination? (If the coordinating group can't affect distribution of funds, it will not succeed.) Is advocacy involved? What groups should lead USDA-wide coordination? How can other groups (EPA, FDA, CDC, DoI, DoD, etc.) be involved? We need to clarify "coordination" before we go into breakout groups.

Further Large-Group Discussion of Biological Control Coordination

• Funding component: We have to coordinate dollars, i.e., the authority to move dollars. • Regulation component: We have to coordinate the authority to regulate a program and decide where the money goes; to prioritize, identify successes, chunk resources around - otherwise it is just distributed wherever the power bases are. • Education component: Make it clear who is responsible for parts of a program.

• Other models of coordination? • The TAG model. • The NBCI Customer Advisory Group model. • Coordination is almost a daily activity. It's networking, it's communication - this level works well at scientist level, but above that managers can do only so much. • Consortia models have gathered resources and funding. Representatives from various entities prioritize problems then try to find funding. • Is there a need for authority in consortia? • Will Congress let us pool money in a single pot? Probably not.

• What about the concept of a council that reports at the Department level to make recommendations? This is modelled on the Biotechnology Council that has a charter and discusses biotech issues. Agencies still have the authority to develop policy. Agencies bring issues to the council through representatives on the council. This allows for a forum at the Departmental level. It must be answerable to a high-enough level in the Department.

• Do we have a unified USDA policy so we can set some goals? • NBCI has written a biological control policy (see *White Paper*, Appendix 1) that was accepted by APHIS. It has been adopted by IOBC and NAPPO. USDA has not adopted a biological control policy. We must have a strategic plan for biological control in USDA. • What about the private sector? Would there be opposition to putting biological control as the first option to be considered where appropriate? • The Department has a clear policy regarding IPM; biological control is addressed as part of that. Do we need a separate policy just for biological control? • If we call biological control simply one tool among many, it will get pushed off to the side. We need to push biological control to the forefront.

• Have we defined biological control? • No. Let's talk about concrete steps that can be taken. The definition is more political than scientific. • All BBTs are pest-specific, for the most part: one solution for one pest.

• There must be coordination and the end result must be control of the pest.

Breakout-Group Discussions of Coordination

Participants were divided into seven groups to discuss what is needed to better coordinate biological control in USDA. The following questions were posed to participants:

1. What should be the goals for coordinating biological control in USDA? (Why coordinate biological control? What do you want to achieve through coordination?)
2. What areas should be coordinated? (Domestic and overseas research, development of biological control, biological control implementation, regulations?)

3. What are the coordination needs and potential areas for delivery of needs?
4. What are the barriers and opportunities for coordination in USDA?
5. What should be the components of a USDA priority-setting, planning, and bench-marking system in biological control?

Representatives of each group later met to compile recommendations into a summary list. (A complete list of recommendations from each group is detailed in Appendix 5.) The summary list was presented to the entire group and modified as requested. The final synopsis follows:

SESSION I SYNOPSIS: Biological Control Coordination in USDA

What should be the goals for coordinating and facilitating biological control in USDA?

- Increase efficiency and effectiveness.
- Avoid duplication or manage healthy duplication.
- Identify gaps and fill them.
- Take advantage of economy of scale by sharing resources/facilities (e.g., quarantines).
- Improve communications with stakeholders. (Document who does what and how the biological control system works; describe agency roles, facilities, personnel. Provide "one-stop shopping" for regulatory issues.)
- Anticipate and identify potential issues and questions (ethical, social, economic, regulatory, legal) early in the R&D process - and prepare answers.
- Achieve consensus re: research, regulations, and priorities.
- Facilitate the priority-setting process with grassroots input.
- Increase funding. (Identify and attract new funding sources.)
- Reduce regulatory bottlenecks, e.g., share data sets among agencies, coordinate required paperwork, etc.
- Stimulate intellectual synergy and teamwork.
- Increase accountability.
- Increase awareness and commitment ("buy-in") among agencies, the public, Congress, and the White House.
- Ensure continuity in programming and organization (but keep flexibility).
- Improve documentation of biological control and make it readily available.
- Provide leadership and structure to focus biological control coordination.
- Improve international coordination of biological control programs.

A potential mechanism for reaching those goals is to establish a biological control coordinating body:

- Located at the Department level;
- With representation (i.e., people with authority) from key agencies within the Department;
- Including representation of the scientific disciplines involved in biological control;
- Including a mechanism for user input;
- To collect information and make linkages among agencies and users ("information brokering");
- To facilitate a priority-setting process that: 1) balances input from users with input from agencies (i.e., encompasses bottom-up and top-down approaches); and 2) identifies and focuses projects;
- To assist scientists in making linkages outside their normal operating arena;
- To champion biological control within the Department and beyond;
- To organize support from state Departments of Agriculture.
- Whoever serves on this body must have at least a portion of his/her time dedicated to this responsibility.

What do we need to coordinate and facilitate?

- Research programs (including foreign exploration);
- Field delivery/implementation programs;
- Technology transfer;
- Biological control activities within each USDA agency;
- Political clout;
- A systematic protocol/approach to biological control (to provide stakeholders with a program's "big picture" from the very beginning);
- Accountability for biological control projects;
- Solicitation and allocation of funds (particularly over the long term);
- Projects coming out of the grant programs (except for those that are linked to agency missions).

SESSION II: Biological Control Regulation in USDA

PANEL PRESENTATIONS ON BIOLOGICAL CONTROL REGULATION

Strategic Regulations and the Advance Notice of Proposed Rulemaking

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WRITTEN ABSTRACT: In the United States, we do not regulate solely on the process by which a product is developed, independent of risk or uncertainty. The question of what constitutes unreasonable risk in the broader sense usually addresses food safety, human health, or the environment; and particularly evaluates risks regarding plant and animal pathogens or carcinogens. The Federal Plant Pest Act of 1957 (FPPA) is such a risk-based statute. Usually, the most contentious regulatory issue is one of scope; what will be covered by the regulation or what should be evaluated to assure that the degree of risk is known. Under the FPPA, the triggers by which APHIS evaluates an organism are: plant pest risk; plant pest characteristics; and the degree of uncertainty or familiarity associated with an organism. In addition, what is unreasonable risk and where in the system is the most efficient point to evaluate for that risk is of great importance. For efficiency, issues need to be identified and regulatory decisions need to be made as early in the process of research and development as possible.

We believe that the greatest risks to agriculture and the environment are posed by the potential establishment of certain plant pest organisms that are new to or not widely disseminated within the United States. Hence, to protect American agriculture, any approach to regulating the introduction of organisms that may be plant pests should commence with screening those organisms for potential plant pest risk. We want to have a system that allows researchers to know before beginning an evaluation of an organism for its effectiveness, what we will be looking at regarding plant pest risk and any associated safety issues. Our regulations should do several things: 1) provide verification of the biology of the organism; 2) assess the degree of uncertainty or familiarity we have with the organism; and 3) identify any risks should they be present and identifiable.

Several factors lead to the publication of the Advance Notice of Proposed Rulemaking (ANPR) "Plant Pest Regulations: Review of Current Provisions" (*Federal Register* 61: 50767-50770) including the President's Regulatory Reform Initiative, an Office of Technology Assessment report (OTA, 1993, "Harmful Non-Indigenous Species in the United States"), and a withdrawn proposed regulation (60 FR 5288-5307) based upon that report. The current regulations in 7 CFR part 330.200 were adequate in 1959 when the regulated community consisted primarily of government and academic researchers. However, the range of organisms and intended uses of those organisms has changed and grown dramatically since that time. APHIS now is asked to look at a variety of organisms being proposed for introduction for a variety of purposes. Such organisms include plant pests, parasites and predators for biological control, centipedes, walking sticks, mantises, butterflies, cockroaches, and microbes for soil treatment.

The ANPR is not meant to be a comprehensive review of APHIS' plant pest regulations implementing those acts, but covers four primary issues: 1) the criteria used to determine whether an organism is a plant pest; 2) types of direct or indirect injury or damage to plants; 3) voluntary certification to facilitate interstate movement and use of biological control organisms; and 4) evaluation of the safety of proposed releases into the environment of organisms with plant pest characteristics. The definition of the term "plant pest" found in the FPPA, as amended, is intentionally broad to allow the Secretary of

Agriculture the flexibility to respond appropriately to a wide range of needs and circumstances to protect American agriculture against foreign pests. This language contains no reference to such a thing as a "direct" or "indirect" plant pest. These terms only apply to the effects caused by plant pests.

Input is needed on the scope of organisms that should be reviewed to see if they are plant pests or present a plant pest risk. For the regulations to be flexible, they must be updated periodically based upon experience with the organisms being evaluated. We want to evaluate based upon risk; document that risk or lack of risk; and exempt efficiently once lack of risk is identified. In the past we have used various approaches in determining which kinds of organisms we should review and how we make that determination. Before proceeding on any path to revise and align our procedures based upon our current thinking, we want to assure that the approach outlined in the ANPR is valid and that all stakeholders have an opportunity to comment on this and certain other approaches we are considering.

APHIS is committed to seeking input and devising new and appropriate approaches for meeting the research, commercial enterprise, and environmental needs that are currently in demand. We feel that the initiation of voluntary certification standards introduced in this ANPR is an example of such a new approach that needs to be considered by the regulated community. The proposal for voluntary certification is intended to begin addressing the issues related to interstate movement for release into the environment of invertebrates and pathogens that are *not* plant pests, including what certain industry groups refer to as "marketed beneficial arthropods." We are proposing the development of a voluntary, cooperative program involving Federal and State agencies, biological control producers and distributors, and the biological control research community to develop standards for and oversee the movement and release of organisms used for the biological control of plant pests. We believe that such a program could be established under our existing statutory authority to facilitate movement or provide product verification.

For consistent and planned results, regulations should be developed and applied strategically. Strategic regulations contain identifiable, science-based triggers that are consistent, easily understood, and transparent. Such regulations account for not only the evaluation of risk versus safety, but also address product verification/utilization; safe technology transfer; economic competitiveness; international harmonization; and global needs and acceptance. In addition, they are effective and responsive. The ANPR provides an opportunity for input before any regulations are proposed. Thus, we need your input. Are the questions and approaches we have posed adequate? Do they represent risk? Is more required?

OVERHEADS

Strategic Regulations:
1) Identifiable, science-based triggers that are consistent, easily understood, and transparent;
2) Effective and responsive - flexible and dynamic;
3) Meet domestic and international needs.

United States:
* Does not regulate based upon process only, independent of risk or uncertainty.

Regulation:
* The intersection of scientific risk assessment and product evaluation; and
* Has to adjust and change rapidly with advances in both.

Federal agency - Implement risk-based regulatory requirements:
* Assure safety and facilitate technology development and utilization by removing regulatory uncertainty.

Decision of Safety:
* Not the final answer;
* Informed choices will be made on the basis of the best science available;
* The process will be carried out in the open.

Advance Notice of Proposed Rulemaking (ANPR)

Issues covered by the ANPR:
* The criteria used to determine whether an organism is a plant pest;
* Types of direct or indirect injury or damage to plants;
* APHIS' role in facilitating the interstate movement and use of biological control organisms;
* Evaluation of safety of proposed releases into the environment of organisms with plant pest characteristics.

Plant pest characteristics:

* Feed upon, infect, or parasitize living plant tissues;
* Feed on, infect, or contaminate plant products;
* Transmit plant pathogens;
* A secondary parasite, pathogen, or predator of a primary natural enemy of a herbivore or plant pathogen;
* Adversely affect commercially important pollinators or important herbivores or plant pathogens that control weeds.
* Identity - by recognized authority *or* poorly understood

Federal Plant Pest Act (FPPA):

"...any living stage of any insects, mites, nematodes, slugs, snails, protozoa, or other invertebrate animals, bacteria, fungi, other parasitic plants or reproductive parts thereof, viruses, or any organisms smilar to or allied with any of the foregoing, or any infectious substances, which can *directly or indirectly injure or cause disease or damage* in any plants or parts thereof, or any processed, manufactured, or other products of plants."

"Direct or indirect injury or damage"

* *Past*: All negative impacts of all organisms within food chains where plants are the primary producers. Evaluate all potential disturbances within food web: 1) Direct - herbivores and plant pathogens cause direct plant injury; 2) Indirect - parasites and predators.
* *Considering*: Impacts within a food chain that negatively affect plants or plant products: 1) Direct - herbivores and plant pathogens cause direct plant injury; 2) hyperparasites that suppress the effectiveness of parasites, predators, or pathogens that reduce damage to plants; and organisms that adversely affect pollinators.

Voluntary Standards

* *A cooperative program*: * Federal and state agencies; * biological control producers and distributors; * biological control research community.
* *Establish and promote compliance*: * Set of voluntary or consensus standards; * Interstate movement and release into the environment of organisms used in the biological control of plant pests; * Document produced in a similar manner to NBCI "Strawman."

Assessing the risk of release of organisms possessing plant pest characteristics:

* Feed upon, infect, or suppress the target or related species?
* Effects on non-target plants
  - Arthropod: Deposit eggs? Species closely related to target? Eggs hatch and immature stages feed upon and complete development? Immature stages complete development on other plants? Adults infertile?
  - Plant pathogen: Spores/propagules germinate and penetrate? Do disease symptoms or signs appear? Does infection result in viable spores or infective units?
* Probable ecological range overlaps native plants related to target species?
* Closely related to other species or strains that exhibit narrow or broad host specificities?
* Threatened or endangered species - feed upon, attack, infect, or otherwise adversely impact?

Additional comments:

Regulations must adjust and change rapidly with advances in scientific risk assessment and product evaluation. Regulators must frame the questions the scientists answer. We must have a legal process with scientific input.

In a Decision of Safety, evaluations must be based on risk. We must have performance standards, and we must document risk or lack of risk. We need coordination of national scientific principles.

RE: ANPR - APHIS has no category for "indirect plant pest." What would constitute indirect plant injury/risk? APHIS wants participant input so it will know how to evaluate this.

EPA Regulatory Responsibility for Biological Control

Bill Schneider, Environmental Protection Agency, Office of Pesticide Programs, 401 M St. SW, Washington, D.C. 20460

TRANSCRIPTION: The EPA regulates biopesticides in the Biopest and Pollution Prevention Division (BPPD).

How does BPPD regulate pesticides?

The Federal Insecticide, Fungicide, and Rodenticide Act (FIFRA) defines pesticide: "any substance or mixture of substances intended for preventing, destroying, repelling, or mitigating any pest, or intended for use as a plant regulator, defoliant, or desiccant...." EPA must ensure that a registered pesticide "will not generally cause unreasonable adverse effects on the environment." This includes some unexpected things like chemistries that induce plant reactions, or chemicals that control algae in ponds - so, many times *intent* is what makes it a pesticide.

Microbial pesticides: 40 CFR 152.20 - All biological control agents are exempt from FIFRA, except Eucaryotic and Procaryotic microorganisms, and viruses. (Nematodes, parasitic wasps, spiders, mites, etc., are currently exempt from FIFRA.)

FIFRA regulatory actions:

* Registration (commercial pesticides)
* Conditional registrations (requires public interest finding)
* Experimental use permits (more than 10 acres of land or one acre of water; any food or feed use)
* Notifications of small-scale field testing (certain genetically engineered and nonindigenous microbial pesticides)

This system is aimed toward commercial use, so some mechanisms for biological control organisms don't fit well. The "experimental use" clause is designed to gather data for registration of a commercial product.

Federal Food, Drug and Cosmetic Act regulatory activities:

* EPA sets tolerances (residues)
* Most biopesticides have exemptions from requirements for a tolerance
* 40 CFR 180.1011 controls *Bt* manufacturing processes (can be used for other purposes)

Risk Management: risk assessment; benefits assessment; risk mitigation

* In new pesticides, benefits are usually theoretical.
* Use standard scheme for risk assessment (hazard x exposure = risk).
* Required to look at risk to non-target species (including threatened and endangered species).

Data Waivers: Inappropriate data requirements may be waived (EPA fairly liberal):

* Registrant must furnish scientific justification (similar microbials are known not to cause effects, test cannot be performed with this type of microbial, organisms known to cause positive effects).
* Registrant must furnish support information (complete literature search, submit articles, expert testimonial, unsuccessful test data, alternative test data).

In some cases EPA performs benefits assessments.

Risk mitigation

If Hazard: remove/limit toxic components, change formulation.

If Exposure: modify use rates, patterns, etc.; label for application restrictions; change formulation.

EPA exemption:

* Applies only to FIFRA (tolerances required if residues are in or on food or feed)
* Listed pesticides are exempt because EPA "has determined ... that they are adequately regulated by another Federal agency." If not, "the Agency will revoke this exemption."

Discussion: • A microbial can be used as a classical (introduced) biological control, or as augmentative (native) biological control. We need to resolve which regulations apply. • EPA considers all microbials as official pesticides unless it has exempted them. • Who's in charge: APHIS or EPA? We don't know if we're testing, collecting data, and filling out paperwork appropriately. We need to remedy this situation.

Consolidated Statutes: Provisions Concerning Biological Control Organisms

Presented by *Sally McCammon*, Science Advisor, USDA-APHIS Office of the Administrator, Rm. 316-E ADMB, Washington, D.C. 20250

WRITTEN ABSTRACT:

1. History

The proposal to consolidate the plant and animal quarantine laws grew out of an oversight hearing on activities and programs of the Animal and Plant Health Inspection Service (APHIS). The hearing was held by the House Committee on Agriculture, Subcommittee on Department Operations, Research, and Foreign Agriculture in July 1983. At that hearing, Congressman George Brown (D-CA) directed the Agency to develop a proposal to consolidate, streamline, and modernize those laws. The result was two draft bills: The Plant Protection Act (PPA) and The Animal Health Protection Act (AHPA). Together, these two proposals would eliminate and replace 28 laws dating back to 1884. On the plant side, those laws include the Federal Plant Pest Act, the Plant Quarantine Act, and the Federal Noxious Weed Act. On the animal side, the laws that would be eliminated include a series of laws passed beginning in 1884, and known collectively as the animal quarantine laws.

In 1988, a second oversight hearing was held and the request for proposals was renewed by Congressman Brown. In 1990, the proposals were cleared by the Administration and sent to Congress for the first time as part of the Department's farm bill initiative. Hearings were held in the House and the proposals received generally favorable reviews. However, it was late in the session and the proposals died when Congress adjourned. They were resubmitted to Congress in August 1995.

2. Farm Bill

During the Farm Bill process, a number of issues were raised by several different groups -- the American Association of Nurserymen, the Exotic Pest Plant Councils (EPPC), and the Association of Natural Biocontrol Producers (ANBP). We were requested by the Agriculture Committees to work the issues out and come back to them.

We spent the next year working with the various groups as well as with several State officials.

3. Issues

In general, issues differed for each group and, in some cases, the concerns counterbalanced each other. For example, biological control producers wanted inspection and seizure authorities to be relaxed and the Nurserymen wanted us to maintain our ability to assess risk and address it while not becoming an impediment. Our goal was to find the balance.

Biological control producers wanted:

* A more positive focus (do not define biological control organisms as plant pests).
* Emphasis on our role as facilitators in support of commerce.
* To decrease the burden imposed by regulation.
* To ensure that any regulation is science- and risk-based.

4. Current Draft

The current draft:

* Refines the proposal by adding a new definition of biological control based on the definition under the International Plant Protection Convention. It also separates the definition entirely from the definition of plant pest. This changes the entire focus from negative to positive and places the correct emphasis on biological control as a beneficial method.

* Contains language that will focus on the need to facilitate commerce where there is no risk. For example, we added provisions that clarify the Secretary's authority to allow for organisms or groups of organisms to be exempt from regulation once it is determined that they do not present a risk. In addition, we added provisions clarifying an individual's right to petition the government to have an organism added or removed from regulation.

* Contains language in the findings that emphasizes the need to facilitate commerce in beneficial organisms.

* Contains language that would authorize the Secretary to cooperate with States in carrying out industry-driven programs that are focused on ensuring the health, quality, and marketability of products (similar to the National Poultry Improvement Plant in VS).

All of these provisions had to be balanced against the need to have a flexible framework for the future to allow us to deal with risk situations we may not now foresee and allow the continued protection of farmers and commercial plant producers.

5. Prospects

While we could not accommodate all of the concerns raised by each group, we addressed most issues in the draft proposal or in the accompanying section-by-section analysis and we believe we addressed the most significant issues. Other issues must be weighed against the concerns of those who see themselves as "at risk," and as regulators, we must find the most balanced approach that allows us to carry out our mission.

The negotiations we had resulted in endorsements from the Nurserymen, the National Plant Board, the California Department of Food and Agriculture, and the Florida Department of Agriculture. We do not anticipate that ANBP or EPPC will officially endorse the legislation, but we also do not believe they will raise significant new issues. ANBP appears to be fairly comfortable with the current draft.

As in previous years, when we go through official clearance with the new draft for the next Congress, it will be sent to various mission areas in the Department for review. In the meantime, we will brief the Agriculture Committees on the progress we have made and hope that they will be willing to move with that draft early in the next Congress.

Overview of NEPA Requirements

Carl Bausch and *Nancy Sweeney*, USDA-APHIS -PPQ, 4700 River Rd., Riverdale, MD 20737

WRITTEN ABSTRACT:

A number of environmental requirements -- not just the National Environmental Policy Act (NEPA) and the Endangered Species Act (ESA) -- at all levels of government may apply to permitting and release of biological control agents.

If properly integrated into biological control planning efforts, however, environmental requirements need not add unduly to the administrative burden or frustrate program objectives.

Whether designed simply to inform decision-making or to protect certain aspects of environmental quality, environmental requirements (including publication of documents and the conduct of public processes, as necessary) must be met before release of agents into the environment is authorized.

Consideration of all environmental requirements potentially applicable to a proposed release does not generally occur in the context of review by the Technical Advisory Group (TAG).

In order to meet the timeframe of need to which a proposed release may be responding and to achieve the most cost-effective environmental compliance process, consideration of environmental requirements must precede, insofar as possible, the filing of an application for release.

Consideration of environmental requirements can be efficiently integrated into the pre-filing planning process in several ways, including:

* providing formal guidance for researchers;
* assigning an environmental compliance expert -- someone thoroughly familiar with *all* potentially applicable environmental regulations -- to the TAG; and
* entering into Memoranda of Understanding with other agencies that have jurisdiction over the subject matter (Fish and Wildlife Service, for example).

Additional comments:

Environmental Impact Statements (EISs) come from NEPA. There are plenty of EIS horror stories (i.e., volumes of data generated for a single project), but you don't really have to be afraid - they don't have to be that long. Environmental Assessments (EAs) can be short. APHIS treats these flexibly.

APHIS is striving to prevent the permitting process from being confusing, time-consuming or burdensome. The process goes from an idea, through research and testing, then preliminary permit inquiry, to permit application filed, through the administration process, then to a permit decision. The difficulty is that the environmental considerations and requirements have been concentrated at the preliminary permit inquiry. We need to move the environmental process back to the original research and testing period so a lot of the work is done by the time the project reaches the preliminary permit inquiry.

Re: Section 7 of Endangered Species Act (ESA):

** TAG's Mission is "to facilitate the safe use of biological control agents of weeds in the environment." To do this, it reviews petitions to release agents into the environment. At that point, the Fish and Wildlife Service (FWS) can raise objections if they perceive conflicts with threatened and endangered species. However, we recommend contacting FWS much earlier in the research process.*

** Part of the function of the ESA is to ensure that the release of biological control organisms is not likely to jeopardize endangered or threatened species or their habitats. The mechanism for ensuring compliance is a Section 7 Consultation. It involves:*

- *Species list: Listed, proposed, and candidate.*
- *Biological Assessment: Evaluation of effects of proposed release of biological control organism on endangered and threatened species and their habitats.*
- *Biological Opinion: FWS's opinion on whether the proposed release is likely or not likely to jeopardize endangered or threatened species or their habitats.*

** The Key: Contact the FWS early (e.g., when something's brought into quarantine) to exchange information and educate them about the project.*

USDA APHIS PPQ Plant Pest Regulations: Current Policies and Procedures Pertaining to Biological Control Activities

Robert V. Flanders, USDA-APHIS-PPQ, 4700 River Rd., Unit 133, Riverdale, MD 20737

WRITTEN ABSTRACT: The importation, interstate movement, and environmental release of organisms used in biological control are affected by several Federal laws, including the Federal Plant Pest Act (FPPA), the Federal Plant Quarantine Act, the Federal Noxious Weed Act, the Federal Insecticide, Fungicide and Rodenticide Act (FIFRA), the Endangered Species Act (ESA), and the National Environmental Policy Act (NEPA). The U.S. has not enacted a specific biological control law or regulation, and none of the existing risk-based laws directly or completely address all the challenges inherent in modern biological control activities. However, USDA-APHIS has assumed primary responsibility for regulating organisms used for the biological control of weeds and herbivores through regulations promulgated under the FPPA. These procedures and policies indirectly facilitate biological control endeavors whenever and wherever assessments conducted on the involved organisms have shown minimal or no plant pest risk.

The FPPA enables regulation of the importation and interstate movement of organisms that are plant pests. The legislation defines plant pests as those organisms "...which can directly or indirectly injure or cause disease or damage in any plants or parts thereof, or any processed, manufactured, or other products of plants." By this definition, all organisms being introduced for biological control of weeds are plant pests appropriately regulated under the FPPA. However, there has been much debate about the meaning of "direct" and "indirect" injury or damage relative to biological control agents that attack herbivores. This is a major question being posed in the Advance Notice of Proposed Rulemaking (ANPR) that we hope to resolve with the resulting public input. We are suggesting that those organisms which only attack herbivores not be legally defined as plant pests. USDA-APHIS will, however, continue to excercise considerable regulatory oversight by requiring quarantine processing and pest risk assessment of all imported organisms of unknown or undocumented plant pest risk.

In classical biological control endeavors, the permitting process usually is initiated by an individual who applies for a permit to import unidentified, field-collected organisms of unknown or previously undetermined plant pest risk. A plant pest permit is required for entry of packages of these organisms to the U.S. The permit usually allows entry of groups of organisms relevant to the specific biological control project and always requires receipt by a USDA-APHIS-inspected quarantine facility. USDA-APHIS has drafted physical and operational guidelines for several types of quarantine facilities. They are now being reviewed by internal and external cooperators and will be finalized during the coming year.

Within the quarantine facility, packages received from overseas are opened, unwanted or contaminating organisms destroyed, and the organisms of interest isolated and purified. Once the identity and purity of an organism is verified, the responsible individual would contact PPQ personnel for subsequent determination of plant pest status relative to any subsequent requests for interstate movement or environmental release. To determine if an organism possesses plant pest characteristics, five questions are asked as part of a plant pest risk assessment. The questions are in the ANPR for public comment. An affirmative answer to any of these questions would indicate some degree of plant pest risk requiring continuing regulatory oversight and would necessitate further assessments for interstate movement or environmental release. If all responses are negative and no other Federal laws (especially ESA) are applicable, then the organism would not be considered a plant pest, and no further USDA regulatory oversight in the form of permits for movement or release would be required. In this case, no NEPA documentation is required since there is no Federal permitting action, but subsequent documentation may be required for future subsequent Federal actions (e.g., releases by Federal scientists or on Federal lands).

USDA-APHIS has historically issued courtesy permits for the interstate movement of organisms that we determine not to be plant pests, but which are being moved and released to control plant pests. The regulations provide for the issuance of courtesy permits for the movement of organisms that are not subject to regulation under the FPPA or any other act, as a courtesy to facilitate movement. However, we have received some criticism for issuing any permit that facilitates interstate movement and environmental release when no further analyses of environmental impacts, other than plant pest risk, have been conducted. To fill this regulatory void, we have proposed for comment in the ANPR the development of a voluntary, cooperative program involving Federal and State agencies, biological control producers and distributors, and the biological control research community to oversee the movement and release of organisms used for the biological control of plant pests. We believe that such a program could be established under our existing statutory authority. It could be operated under standards developed through consensus by its participants. We envision the National Biological Control Institute as the organizational unit within APHIS as most suitable for developing, implementing, and having permanent responsibility for such a program.

For organisms that we detemine by the assessment conducted in quarantine to possess plant pest risk, the FPPA does not explicitly enable release to the environment. Indeed, any subsequent movements and activities with plant pests are strictly regulated by APHIS to prevent release to the environment. The only exceptions are where organisms are proposed for release to control a weed. APHIS only allows the release of these organisms when they have been scientifically shown to cause population-level injury, damage, or disease only in a narrow range of closely related plant species. The targeted plant must also be overwhelmingly considered an undesirable weed. To aid in decision-making, APHIS obtains input from a Technical Advisory Group that consists of representatives from relevant Federal agencies. Questions on host specificity are used by APHIS and the TAG representatives to assess the safety of releasing these organisms to the environment. These questions are presented for comment in the ANPR. If a decision is made by APHIS to allow release of a weed biological control agent, then a plant pest permit may be issued following development of NEPA documents. NEPA requirements frequently require consideration of various environmental questions other than plant pest risk, and these other considerations have delayed or complicated some recent weed biological control projects.

USDA-APHIS continues to seek an effective balance between protecting the United States from the introduction of nonindigenous plant pests and facilitating potentially beneficial activities like biological control. This charge places us in a very difficult situation of having to play both gate-keeper relative to plant pests and facilitator relative to such activities as the importation and release of organisms with potential commercial, environmental, or agricultural benefits. We believe that our past policies and procedures have been major contributors to the safety record of research on plant pests and of such endeavors as biological control in the United States. We welcome comments, criticisms and ideas as a vital part of our continuing efforts to guarantee that our policies, procedures and regulations remain effective and relevant.

Additional comments:

Plant pest and plant pest risk need to be addressed.

In 1992, several things occurred that impacted the way we regulate plant pests - prior to that, biological control was pretty well facilitated.

APHIS Organism Permitting personnel: Rebecca Bech replaced Matt Royer as Chief Operating Officer of BATS. We have a team trained in biological control working with permitting now.

OVERHEADS:

Quarantine facility considerations: * Certification approach and permitting; * Guidelines - physical, operational; * Standards vs. specifications; * Inspection; * Training; * Manuals; * Communication.

First Tier Risk Assessment: * Identity confirmed; * Contaminants removed; * Does not feed on or infect living plant tissues; * Does not feed on, infect, or contaminate plant products; * Does not transmit plant pathogens; * Not a parasite or pathogen of a primary parasite; * Does not adversely impact pollinators, beneficial microorganisms, or important natural enemies of plant pests or weeds; * Does not impact endangered or threatened plants or animals.

Flow chart: Biological control of plant pests: Organisms that are not plant pests are only required to have a courtesy permit. (EAs are recommended, however.) We don't have a legal means of dealing with "beneficial" organisms, moving them from the non-plant-pest category. Someone should come up with a risk/benefit assessment for this type of organism.

Courtesy Permit: "The Deputy Administrator may issue permits for the movement into or through the United States, or interstate, for organisms which are not subject to regulation under the FPPA or any other act, as a courtesy to facilitate movement when the movement might otherwise be impeded because of the similarity of the organisms with others regulated under the FPPA. He may likewise issue such permits on behalf of any agency requesting such actions as a courtesy to facilitate movement for organisms not subject to regulation under the FPPA but subject to regulation under some other act."

Flowchart for Biological Control of Weeds:
- Risk Assessment Considerations: Weed Biological Control Agents
  - * Feeding specificity
  - * Oviposition/germination capabilities
  - * Development/infection capabilities
  - * Viability of following generation
  - * Comparison of probable ecological ranges
  - * Specificity relative to related T&E species
  - * Etc.
- Other Concerns/Considerations
  - * Precedence for biological control agents of plant pests
  - * Precedence for weed biological control agents
  - * "Pass-through" quarantine for weed biological control agents
  - * Commercial importations for direct field release
  - * Etc.
- Other Major Developments of Organism Permitting Team
  - * Permit information into database
  - * Permit database available on Web
  - * Expedited species lists (Arthropod Natural Enemies of Plant Pests, Biological Control Agents of Weeds)
  - * FAX Vault
  - * Web page
  - * Quarantine guidelines
  - * Customer service survey

Conclusions:
- * APHIS regulates plant pests. Facilitates biological control.
- * No law or regulations specific to biological control in the United States.
- * Past and present regulations and procedures are major contributors to safety record.

* APHIS continues to evaluate all applications for impacts on T&E species (interactions with FWS)
* Recent concerns are a result of NEPA coupled with changes in plant pest definition.
* Need better communications and public relations.
* Need better written procedures and policies.
* Need better coordination/communication with other agencies/departments.

APHIS Policy on the Long-Term Holding of Quarantine-Significant Plant Pests in U.S. Containment Facilities - December 1995 (*Handout*)

To prevent the introductions of quarantine-significant plant pests into the United States and movements of such pests between States, research should be conducted either in the pests' countries of origin or in specifically regulated areas of the United States where APHIS is conducting a control program for the pest. Quarantine-significant plant pests are defined as plant pests of economic significance that are either not present in the United States or present only in limited areas where a control program is being conducted. Some quarantine-significant pests are listed in the Code of Federal Regulations (Title 7, Parts 300-399). Holding quarantine-significant plant pests in a containment facility for long periods increases chances that they might escape and become established despite the general structural, mechanical, and operational integrity of the facility. Multiple precautions minimize but do not prevent human inattentiveness and equipment failures, and natural disasters are always possible.

Generally, APHIS does not approve the holding of a quarantine-significant plant pest when the proposed containment facility is located in an environment conducive to the pest's establishment. However, APHIS evaluates each permit application on its own merits, and a permit may be issued in special circumstances, such as when the research would lead to methods for predicting or preventing outbreaks, or eradicating the pest from quarantined areas. In such cases the containment facility must be secure, and the pest can be held only until the essential research is completed.

Voluntary Certification
Andrew Rohrer, USDA-APHIS, Senior Coordinator, National Poultry Improvement Plan, 1500 Klondike Rd., Suite A102, Conyers, GA 30207

TRANSCRIPTION: The National Poultry Improvement Plan provides an example of the establishment of a voluntary certification system. People were interested in the idea, goals were set, and APHIS provided the regulatory umbrella. It worked. Although it is a market-driven model, parts of this model are applicable to biological control technology. To get this technology to take off, you have to get some commercialization interest in the products.

The National Poultry Improvement Plan had it its genesis in an association formed in the late 1800s to standardize things like breeds and to research poultry diseases. Industry worked at the state and local level to develop tests and study genetics. Public exhibitions were given. This all became part of National Poultry Improvement Plan. The national program used the best of state and local programs, and developed standards of terminology for all areas of the country. In the mid-1930s the first official National Poultry Improvement Plan was established. Congress appropriated money, Extension helped implement research, and state poultry associations were established. This was all industry-driven.

Today, every state that has participants can elect a delegate to a national committee. Two percent of the Plan's funds come from the national committee, while state and plan participants provide the remaining 98%. The program drives itself - you can't afford not to participate if you're a poultry breeder because you can't sell your product.

Large-Group Discussion of Biological Control Regulations

• The National Environmental Policy Act (NEPA) does not go into effect until organisms leave quarantine. • When a courtesy permit is given, who regulates the organism? • EPA won't require action on non-indigenous organisms acted upon by USDA. EPA's primary concern is for plants. • So, once a courtesy permit is given, we're not regulated by APHIS or EPA processes? • Do non-government scientists have to pay attention to NEPA? • If you're federally funded, you do. • State university people don't know what they have to do to comply with NEPA. • We may need to revisit ARS NEPA procedures to accommodate needs of ARS scientists. ARS is in the process of defining/outlining NEPA requirements for its agency. Many people want a central location to deal with NEPA requirements - "a NEPA shop." • At a minimum, you probably have to do an EA. • Courtesy permits are only to facilitate movement, NOT to release organisms.

• Once you've done a bunch of EAs and EISs on a category of organisms, can you use categorical exclusions? • APHIS is now working with scientific societies on this. A programmatic Environmental Impact Statement could clear up a lot of uncertainties to rationalize the process and get to issues like what controls must be exercised by state people.

• The distinction among trophic levels in risk assessments is antiquated. You can't say that a predator will feed only on herbivorous insects - it may also eat other beneficials. Interactions are very complex. • The same applies to hyperparasites. • Will we have to do extensive studies to determine this? • Re: risk assessments - every permit is looked at by people knowledgeable in this area. Can we determine other actions that may be risky? Maybe this would require more study to reach a determination. We need some sort of leeway to determine each petition. • However, the issue is that determinations have been made more through pressure on APHIS rather than science. We need a conflict resolution process to solve these issues rather than get stuck in paperwork. • NEPA documentation is somewhat of a conflict resolution process.

• If ARS says an organism won't have significant impact, you can still get hit by a lawsuit. But the NEPA process shows that a decision was made with thought and effort. The more you comply with laws and regulations, the less likely it is that you'll lose a lawsuit.

• Risk assessment of pollinators: Will introduced ones outcompete the native ones? We used to have a good program in ARS, but we got one letter opposing introduction of this research on the basis of outcompeting - the next thing we know, we had to close the project. • Those challenges are in reality challenges to NEPA and the decision to release to the environment. Now, the challenge is to ARS: How did you come to the conclusion of release to the environment? It's a challenge to the agency performing the actions, because the permitting agency doesn't have jurisdiction in this area. • Consider these issue when you're doing your research.

• Does TAG still consider T&E at the initial submission of documentation? • No. The critical time to submit to TAG is the first time the weed is submitted for consideration. Find out about T&E species EARLY! There is no precedent in FWS for doing a biological assessment for a biological control agent that will spread. All their work is site-specific. • Now FWS wants to consider mitigation and extensive monitoring. • Regarding awful regulatory situations like that surrounding salt cedar, who can prepare an EIS? • We need to coordinate among ourselves and with others who are potentially affected. There are lots of ways to coordinate. Call the APHIS regulatory lawyers - we can help with some of this coordination. We could crank out an EIS, but... • In a situation like the salt cedar issue, it would be a waste to prepare an EIS when ultimately this decision will be made way beyond APHIS because it's an interagency squabble now. You should do an EA (addressing mitigation) to address the NEPA issues. T&E still must be addressed. If you have another agency that's requiring another EIS, bring them into the process so they're satisfied by the process the FIRST time. • Part of the problem in the salt cedar situation was unfamiliarity with the procedures. • A solution to the salt cedar issue must be found immediately. This is about advocacy and conflict resolution.

• Please give your input on the ANPR.

• Is APHIS the only place that should centralize the NEPA process? Should other agencies do the NEPA process? • There should be a centralized process that deals with non-plant pest NEPA requirements. • So, should we have a higher-level decision-making process that covers liability of all USDA agencies? • We need to coordinate and

cooperate at a higher level. • Let's not duplicate our efforts. Today each agency has its own way to implement NEPA. • The EPA review of pesticides precludes NEPA = functional equivalent of NEPA review.

• Moving insects from one state to another we encounter a patchwork of state regulations. • Can states be included in a high-level coordinating committee? • This committee could be advisory to state Departments of Agriculture.

• At what (hierarchical) level should the FWS be contacted? • If multiple FWS areas are involved in an issue, contact the Washington office. Otherwise, start at the regional level.

• Regarding the ANPR: Does the test for an organism as a plant pest affect commerically important plant pollinators? Is its intent to cover honeybees? • This doesn't regulate pollinators at all.

• When would APHIS get involved? • As early as possible. So scientists would notify APHIS that they'd be sending in an application in a couple years.

• Precedented organisms need to consider a changing Endangered Species list; researchers need some guidance in producing EAs.

• The 526 forms state the purpose of an insect. They're signed by state, feds, etc. Isn't this a Memorandum of Understanding?

• An EA is a short document. Scientists should write them because they are the people who know the details. NEPA is standardless, however. Ideally, standards are agreed upon by a community as a whole.

Customer-Identified Needs for Biological Control Regulation: The NBCI-Facilitated "Strawman"

E.S. Delfosse, Director, USDA-APHIS National Biological Control Institute, 4700 River Rd., Unit 5, Riverdale, MD 20737

TRANSCRIPTION: NBCI is within USDA-APHIS. It operates as an organization with customers and has a Customer Advisory Group. The customers said biological control regulations are inadequate. Regulations must facilitate biological control.

Why regulate biological control? To provide a mechanism to examine the safety and efficacy of biological control agents.

The NBCI Biological Control Policy Conceptual Model starts with a philosophical viewpoint. This leads to appropriate policies. Then actions can be taken to implement those policies. (Philosophy➔Policy➔Action)

The ideal relationship between risk and regulation is to prove positives (make inferences based on scientific data); conduct a risk assessment (consider sequential, phenology/event-based, conditional probability); regulate agents in proportion to the risk they present to non-target species; and consider benefits.

Customers' Wish for APHIS Regulators:

* Become facilitators of the process (make contacts, publicize plans, help get through federal processes); work with the customers, come up with protocol for EAs (although charge customer with writing draft EA); facilitate peer review - then return reviews to customer to come to terms with.
* Place most emphasis on unprecedented agents
* Base decisions on science
* Involve established experts in peer review of applications
* Share the process with customers
* Implement minimum standards (don't over-regulate a safe technology)
* Cultivate partnerships

There are two global models for regulation:

* Gatekeeper model: command and control, lack of transparent standard, not based on science, regulation not proportional to risk, poor customer service.

* Facilitator model: Entrepreneurial brokering, standards transparent and science-based, regulation proportional to risk, extensive peer review by partners, short turnover times for review, high customer service.

OVERHEADS

The "Strawman":

Is not official APHIS policy or a prelude to an APHIS ANPR.

It is a draft scientific document for peer review by colleagues which was facilitated by NBCI for 5 years. (>100 external & >200 internal meetings with colleagues.)

The Charge to NBCI by APHIS Administrator Bob Melland was to review how APHIS regulates biological control. He issued five terms of reference for the review: 1) Examine regulatory authority, policy and regulations; 2) Clarify responsibilities; 3) Document current system; 4) Consult widely with customers on what is needed; 5) Propose a mechanism for continued, meaningful customer involvement.

Outcomes of listening to customers included: Entrepreneurial brokering development of a conceptual model of regulation; new standards transparent and science-based; regulation proportional to risk; peer review by partners into the future; short turnover times; high level of customer service.

The 10 Points of Most Concern to Customers Used in Developing the Conceptual Model (the "Strawman") were:

1.) Modifications to the FPPA
* Authority over non-phytophagous organisms questioned
* Get rid of the vague and standardless *indirect plant pest* legal definition
* Don't legislate huge changes to APHIS authority
* Change implementing procedures even if no changes are made to the FPPA
* Add three new definitions: "beneficial organisms," "precedented organisms," and "notification"
- *Beneficial organism* definition: Any organism that could potentially produce as a result of its use as a biological control agent a net benefit to agriculture, the environment and/or the economy.
- *Precedented organism* definition: An organism for which a permit has been granted in the past by APHIS and/or by one or more State Departments of Agriculture for importation, interstate movement, or release into the environment.
- *Notification* definition: A process initiated by the customer to APHIS via a letter, facsimile, or e-mail message (or telephoning a request to be followed up by a letter, facsimile, or e-mail message) that a precedented or unprecedented organism is to be (1) imported to a USDA-approved facility; or (2) moved interstate between USDA-approved facilities; or (3) a precedented organism is to be released into the environment.

2.) Notification for Importation and Interstate Movement
* Covers both precedented and unprecedented organisms
* Identity of organism must be made by a qualified taxonomist
* Identity not necessarily to species
* Organisms must be sent as a "pure colony/culture"
* USDA-approved facility must have SOP

Data Requirements
1. Notifier's name and contact information
2. Where and when organism to be moved
3. Permit number and date if for a precedented organism
4. Scientific and common names of organism, stage and number moved, and target organism or site
5. Authoritative identification of organism
6. Reference to any known, significant, catastrophic, population-level damage to non-target species from the organism, or a statement that no such effects are known.

3.) USDA Approval of Quarantine and Containment Facilities
* A new process of facility-based approval rather than a case-by-case organism approval
* USDA-approved facility must have SOP
* Once approved, all organisms requiring a similar or lower level of containment should be moved by notification

4.) Notification For Release of Precedented Organisms

Data Requirements

1. Notifier's name and contact information
2. Permit number and date issued
3. Scientific and common names of organism, stage and number, where originally collected, and authoritative identification of organism
4. Scientific and common names of target species (or host and site of action for antagonists and competitors)
5. Date(s) and location(s) of proposes release(s)
6. Certification of no significant, catastrophic, population-level damage to non-target species from the organism, or a statement that no such effects are likely, or potential targets evaluated.

5.) Commercial Biological Control

* Most agents have been precedented for many years, with no documented non-target effects
* Avoid over-regulation of low-risk species
* Need standard for direct field release
* Emphasize *product control* not *process control*
* *Identity* is same standard as other agents
* *Purity* restricted to non containing listed plant pests, hyperparasites/diseases of host, or viable host material; or SOP in place
* APHIS to conduct random checks
* APHIS has no role in regulating quality and efficacy, which are best determined in the marketplace

Data Requirements

1. Notifier's name and contact information
2. Permit number and date issued
3. Scientific and common names of organism, stage and number, where originally collected, and authoritative identification of organism
4. Scientific and common names of target species (or host and site of action for antagonists and competitors)
5. Certification of no significant, catastrophic, population-level damage to non-target species from the organism, or a statement that no such effects are likely, or potential targets evaluated

6.) Release of Unprecedented Organisms

* Regulation should be proportional to risk to non-target species, especially T&E species
* APHIS should facilitate examination of risks in an open peer review process, emphasizing liaison
* Two-tiered system proposed: plant-"feeders" and non-plant-feeders
* Host-specificity testing required for plant-"feeders"; optional for others
* APHIS should develop with partners specific, transparent standards
* Use benefit:cost where data available

Data Requirements: Applicant

1. Name and contact information
2. Contact information for facility involved

Data Requirements: Target

1. Scientific and common names of target, or host/site of action for antagonists and competitors
2. Native range and, if determinable, probable center of origin
3. Current and estimated potential distribution in North America
4. Related species in North America (within reason)
5. Pest status, including other management options

Data Requirements: Agent

* Tier One: Plant-Feeders or -Attackers

1. Scientific and common names of agent, and name and qualifications of identifier
2. Native range and, if determinable, probable center of origin
3. Brief biology, including MOA and control potential
4. Proposed source (country, laboratory, etc.)
5. Related species in North America, and summary of host range and potential risk to non-target species
6. Possible interactions with existing programs
7. Host-specificity testing program
8. Program collaboration and monitoring details

* Tier Two: Non-Plant-Feeders or -Attackers

1. Scientific and common names of agent, and name and qualifications of identifier
2. Native range and, if determinable, probable center of origin
3. Brief biology, including MOA and control potential
4. Proposed source (country, laboratory, etc.)

5. Related species in North America, and summary of host range and potential risk to non-target species
6. Possible interactions with existing programs
7. Program collaboration and monitoring details

7.) Exclusions from Regulatory Oversight
* APHIS should facilitate a process under NEPA to determine of biological control agents quality for *categorical exclusion*
* Use the lists of organisms proposed after scientific peer review as the starting point
* Exclude all precedented organisms that meet the *no catastrophic, documented damage at the population level* standard
* Exclude all biological control agents indigenous to North America
* NBCI should facilitate a workshop on this topic

8.) Conflict Resolution Procedure
* APHIS should facilitate objective, science-based, speedy resolution of conflicts
* Choice of target or agent, or denial of permit the usual causes of conflict
* Customer-driven procedure:
1. Define the problem
2. Assemble a conflict resolution resource package
3. Impanel an ad hoc review group
4. Prepare a draft recommendation
5. Announce a final decision
6. Implement decision

9.) Enabling Legislation for Biological Control?
* Biological control in the USA is regulated by a series of laws passed for something else
* Most countries regulate biological control by a combination of old quarantine and newer environmental laws
* This results in legal terminology, rather than an open, scientific process
* A new law that enables biological control should be considered for the USA
* The only country that has passed enabling legislation is Australia (Australian Biological Control Act 1985)

10.) Customer Service
* Clinton Administration set customer service as a goal, and provides guidance on how this should be done by Federal agencies
* APHIS Biological Control Philosophy commits the agency to a consultative process that places biological control as the first option for pest management where appropriate
* Transition from policy to implementation in APHIS has been slower than customers expected: need *User's Guide*, standards, etc.

Additional comments:

Where's the TAG in the "Strawman" model? • It's not specifically discussed in the Strawman *because there was no consensus about this use of TAG for non-"phytophagous" biological control agents. However, use of an expanded TAG was suggested by customers, and is now included in the model.*

Balancing Risks and Regulation

R. James Cook, Research Leader, USDA-ARS Root Disease and Biological Control Research Unit, Pullman, WA 99164-6430

WRITTEN ABSTRACT: As with any environmental intervention, there is virtually no limit to the questions that can be raised about potential unwanted adverse effects of organisms deliberately released/introduced/applied for the purpose of providing biological control of pests in agriculture and forestry. Yet biological control is one of the few if not the only pest control strategy for which, as a general characteristic, effects on nontarget organisms rarely can even be measured. By comparison, pest control strategies such as tillage, crop rotation, field burning, soil fumigation, changing varieties, and most other practices used for pest control have major and readily measurable effects on nontarget as well as the target organisms.

Public and private research organizations must

become more efficient in the development and implementation of biological control to meet the needs and expectations for pest and disease management within the context of sustainable growth of agriculture. Chemical companies are finding ways to cut the time required from discovery to bringing a new pesticide into the market approved and registered. Similarly, plant breeders through "shuttle breeding," marker-assisted selection, and other innovations are reducing the time required to develop new disease- and pest-resistant cultivars. In contrast to these trends, all indications are that, in spite of an enormous knowledge base, the time required from discovery to implementation of biological control is not decreasing and may be increasing.

The apparent trend toward longer rather than shorter time from discovery to implementation of biological control is particularly worrisome in view of the given inefficiency inherent with biological control compared, for example, to chemical control. Many different biological control agents typically are required to control the spectrum of pests or diseases that can be controlled by a single chemical. Considering the diversity of pests and plant diseases in the United States, full exploitation of biological control as a component of IPM will involve the release/introduction/application of thousands and more likely tens of thousands of biological control organisms. This reality, and the realities of 1) the ever-changing pest/disease pressures on crops, livestock, and the environment, 2) the essential role of public-sector research in biological control research and development, and 3) declining public resources for agricultural research and education, clearly we must find more efficient ways to develop and implement biological control. We must succeed since healthier crops, livestock, and forests are among the few means available by which to increase plant and animal productivity without requiring more land, water, or fertilizer.

Regulations are an essential part of the use of biological control, but like all other aspects of the research and development (R and D) process, regulations must do the job expected while becoming more streamlined and efficient. It is not efficient for nations to restrict their search for useful new biological control agents to their indigenous or naturalized organisms, or to duplicate work already done in another country, yet this happens or can happen when regulations delay or effectively prevent the importation and release of nonindigenous organisms for biological control. Furthermore, any request for additional information on risk(s) must be made with the realization that providing this information increases the cost, lengthens the R and D process, and ultimately reduces efficiency of biological control research and development.

The current U.S. system and infrastructure for discovery, development, approval, and implementation of biological controls is badly in need of modernization. This modernization should include the development of generic protocols and a timeframe for the R and D process from discovery to implementation. It should also include scientifically-based frameworks for early and rapid identification of potential adverse effect and ways to manage any adverse effects. The modern-day protocols for development and use of new chemical pesticides and new varieties of crop plants should be examined as models of what could also be accomplished with modernization of the U.S. infrastructure for development and use of biological control.

Additional comments:

We have a FIFRA filter: as far as moving microbials into application, FIFRA filters out anything that's not big enough to be commercially viable. The result is that a lot of good things don't get into the system.

Is it possible that this is only the tip of the iceberg in the way of risk-related questions that can be asked? We have to be on the front end of the curve and anticipate the questions that will be asked. We have to identify possible negative outcomes early and identify reasonable risk.

Regulatory procedures shouldn't force scientists to duplicate each other's work. Why should I repeat everything that's been done in Australia?

Assessing risk: Biological control as an approach to pest management may be the only approach where we can hardly measure non-target effects. Some are so subtle. You have to put it in perspective. There are non-target effects of NOT controlling plant diseases. Agriculture itself makes a big impact on the environment, but can also provide great positive effects.

My technology has to go into the marketplace. We need brokers, facilitators, cheerleaders.
The benefit side of risk:benefit analyses need to be a bigger part of the regulatory process. We can make a case for benefits other than increased yields. We always need to discuss the effects of NOT controlling a pest and the environmental benefits of pest control.

We have to be sensitive to the understanding of the public. On one project we spent five weeks on education of county commissioners, farmers, etc. We explained what we were doing and tied it to wheat improvement rather than a "biopesticide." Tie projects to areas of familiarity. We have to think about marketing.

White Paper Recommendations for a Regulatory System for Biological Control

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OVERHEADS

Recommendations:

* Reasonable regulations and procedures (including importation, interstate movement, introductions into the environment.
* Regulatory oversight should be: science-based; transparent and easily understood; consistent, yet flexible; responsive (communication is key); meet domestic and international needs; effective.
* Effective regulatory oversight provides: assurance of safey to the environment and human health; public confidence in the technology; public support for the technology.
* Evaluating the environmental impact of releases of biological control agents: evaluate before release; evaluate short-term after release; evaluate long-term after release.
* *Biological control agents should be regulated differently from chemical pesticides.*

* OTA options for changes by APHIS:
  1. Streamline the permitting process and design a balanced regulatory system.
     - Increase input from all stakeholders
     - Clarify regulation of nematodes
     - Technical Advisory Group (TAG)
     - Develop mechanisms to use input from outside government for making decisions (TAG or other means)
     - Post-release monitoring
     - Document regulatory processes
     - Convene scientific panel to evaluate precedented releases
  2. Consolidate all APHIS plant protection statutes in a single package.
  3. Insufficient justification for a separate act to regulate biological control.
  4. Assurance of "quality and purity" of biological control agents.
     - No statutory authority for APHIS to regulate.
     - Industry moving toward voluntary standards.
  5. Congress could increase private sector involvement in the production of biological control agents used in federal programs.

Breakout-Group Discussions of Biological Control Regulation

Participants were divided into seven groups to discuss what needs to be included in a biological control regulatory system. The following questions were posed to participants:

1. What should be the goals for regulating biological control in USDA? (Why regulate biological control? What do you want to achieve through regulation?)
2. What should be the level of regulation in biological control given the risks?
3. What needs to be included in a biological control regulatory system to address the following:
   * First-time introductions of nonindigenous biological control agents? * Precedented biological control agents and interstate movement? * A conflict resolution process between the regulated and regulator? * Quarantine and laboratory facilities? * Other issues?

4. What are the barriers and opportunities for regulating biological control in USDA?

Representatives of each group later met to compile the ideas into a summary list. (A complete list of recommendations from each group is detailed in Appendix 5.) The summary list was presented to the entire group and modified as requested. The final synopsis follows:

SESSION II SYNOPSIS: Biological Control Regulation in USDA*

The goals for regulating biological control are to:

- Protect U.S. agriculture, forests, human and animal health, and the environment/ecosystems; and to enhance trade.
- Ensure the public and agricultural community's confidence in the credibility of the regulatory process and safety of biological control (and thereby foster public support).
- Expedite biological control programs, enable programs to proceed safely (by excluding organisms that may harm the environment and accelerating the approval of organisms that are safe).
- Ensure uniform and consistent regulations across states to facilitate importation or movement of biological control organisms across states.
- Provide a mechanism for public and peer review (evaluation) and conflict resolution among competing or conflicting interests on biological control. To safeguard public interests.
- Facilitate timely implementation of biological control by satisfying the legal requirements (plant pest regulations, animal quarantine laws, FIFRA, NEPA requirements, T&E, state, etc.). (If USDA does not regulate, another department will.)
- Reduce burdens to allow commercialism and additional research.
- Bring order to and document the process for biological control development - from research to implementation and application.
- Facilitate availability and distribution of biological control organisms.

An effective USDA biological control regulatory system:

- Is based on sound science;
- Is a streamlined and efficient process;
- Serves as a facilitator / expediter;
- Is integrated across the USDA;
- Provides a clear, understandable, logical road map for proceeding through the regulatory process;
- Asks scientists to prove positives, not negatives;
- Is predictable, consistent, and does not produce ad hoc decisions;
- Has clear authority for plant and non-plant pests, especially regarding release issues;
- Is a customer-friendly process, from discovery to research, transfer, quarantine, release, establishment, and evaluation;
- Maintains the high safety record of biological control;
- Balances regulations with risks;
- Includes a regulatory compliance coordinating unit that functions across agencies to provide "one-stop shopping" for permitting, environmental documentation, and compliance with Lacey Act, NEPA, ESA, state laws, etc.;
- Provides a programmatic Environmental Impact Statement (EIS) for biological control;
- Provides a coordinated EA/EIS that may be used across agencies for biological control agents;
- Initially, satisfies USDA needs and USDA's direct customers, then expands its scope.

What should be the level of regulation in biological control, given the risks?

Amount (level) of regulation needed:

- Minimal regulations to ensure safety; regulations tailored to the target organisms;
- At a level to protect biological control from adverse legal action;
- At a level consistent with and appropriate to risk level;
- Consider benefits - greater benefits may justify greater risks;
- Level of regulation needs to be flexible and adaptive, possibly tiered to consider routine and high-risk agents differently.
- Should not be ad hoc.

Where (level at which) regulation originates:

- APHIS or higher level - whatever level of authority is necessary to get the job done.

- Regulators must have the authority to coordinate all the different regulations impacting biological control.
- Lead Department (USDA) authorized by specific legislation.
- (Look at other models: Aquaculture group, Global Climate Change, IPM, etc.; explore Consolidated Statutes and other regulatory models and the possibility of other biological control regulations.)

What needs to be included in the USDA biological control regulatory system?

- The 10 points of the "Strawman":
  - Modification of FPPA
  - Notification for Importation and Interstate Movement
  - USDA Approval of Quarantine and Containment Facilities
  - Notification of Release of Precedented Organisms
  - Commercial Biological Control
  - Release of Unprecedented Organisms (plant-feeding and non-plant-feeding)
  - Exclusions from Regulatory Oversight
  - Conflict Resolution Procedure
  - Enabling Legislation for Biological Control
  - Customer Service
- with the following additions:
  - Establishment of an interagency coordinating body - including funding for this body;
  - Coordination with Mexico and Canada;
  - Strengthening of a technical advisory group for plant-feeding and insect-feeding natural enemies;
  - Conflict resolution / appeals process: If denied a permit, the issue should be referred to: 1) an ad hoc peer review process outside the regulatory body; and/or 2) an informal process conducted at the lowest possible level, e.g., between the scientist and the TAG member.
  - Definition of "precedented" (progeny of an existing collection/genotype/clone);
  - Maintain a list of organisms that have been permitted/introduced;
  - Clarify the issue of indirect plant injury.
- Other issues:
  - Consistency of regulations: Why are we regulating biological control organisms and not other comparable organisms?
  - APHIS and NBCI need to work together (put turf issues behind them) and focus on the issues and improvement of the process. (Agencies must coordinate within before they can coordinate with each other.)
  - Straightforward and clear protocol for clearing microbial (nonindigenous) biological control agents.
  - Need for a disinterested third party for mediation of conflict resolution.

What are the barriers to regulating biological control in the USDA?

- Form 526;
- Turf among agencies with overlapping jurisdictions (perception of loss of authority/status; lines of authority are vague - who has the authority?);
- Politics within agencies (leading to indecision and avoidance of decision-making);
- Lack of clear policy and leadership;
- Fear of making a mistake that might result in liability lawsuits;
- Lack of business process - everything's done ad hoc - lack of systematic process thinking;
- Inertia within the system - wanting to maintain the status quo;
- Difficulty convincing scientists to accept regulatory positions;
- Lack of fundamental information about the organisms.

Opportunities in regulating biological control:

- To coordinate biological control activities/laws with the states;
- To have this workshop and implement the recommendations;
- To establish a committed partnership of the biological control community;
- To gain greater public recognition and to support the biological control paradigm;
- To provide increased customer service.

** Note: There was much discussion about how these principles were developed at this workshop for biological control of weed and insect pests, but these ideas may be applied to other introduced beneficial insects. The scope of this workshop precluded a full discussion of pollinators and the control of livestock pests. These areas also must be addressed by APHIS as it considers comprehensive biological control regulations.*

SESSION III: Biological Control Accountability in USDA

White Paper Recommendations to Increase USDA Accountability

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OVERHEADS

How can the USDA *become* accountable for biological control, research and delivery?
To whom is the USDA accountable: Administration, Congress, customers, other Federal agencies?
How are research dollars being applied to increase the knowledge base for biological control?
How are gaps in knowledge being identified? Is the biological control research system flexible enough to be able to redirect funds to new and emerging research needs?
How is the USDA providing for an educational system that will enable biological control to be implemented most effectively in the field?
How is the USDA creating and implementing regulations that are meeting the needs of its customers while assuring legal and scientific validity?
How is the USDA receiving customer and user input into biological control funding policies, regulatory issues, and implementation plans? Is this a continual process?

* Accountability implies outcomes (qualitative or quantitative) and reporting. Reporting on total dollars spent in biological control is not enough!
* What are we going to measure?

USDA operations
- Development of coordinating activities
- Customer conferences and other opportunities for customer input
- Regulations modified based on user input and needs
- Interactions with other Federal agencies
- Information availability (Web sites, clearinghouses)
- Clearly defined approaches for obtaining permits or assistance with NEPA
- Number of researchers and Extension agents trained in biological control
- New knowledge generated (pubs, conferences, etc.)

Outcomes in the field
- Number of releases of non-indigenous organisms
- Successful substitutions of biologically based pest control for chemically based
- Increased commercial production of biological control agents
- Higher economic return
- Reduced environmental impact of pest control

* What are the impacted areas for which we can be accountable?

White Paper summary of accountability issues:

* Mullin and Fugere report:
  - TAG should be expanded, and TAG should review all proposed projects.
  - Create a clearinghouse for new projects so they can be announced before explorations and to cover unprecedented releases; therefore, interested parties would comment and cooperators could be altered.
  - ARS Documentation Center compile information and pass to NBCI for dissemination.
  - States should be notified by APHIS of release of precedented species and proposed releases be publicized for comment -- programmatic EIS should be prepared by all USDA agencies, to which EAs could be tiered. EAs should include benefits and risks.
* National Research Council:
  - Coordinated multidisciplinary and interdisciplinary research is needed to develop environmentally based pest management with public oversight to help evaluate risk.
* Office of Technology Assessment (OTA):
  - Funds from land management agencies bypassed through to ARS for operational needs in biological control.

- Congress could direct ARS to allocate a proportion of BBT funds to competitive grants for collaborative research to field applications. Farmers' and other users' needs assessed at the inception of the research.
- Congress could direct ARS and CSREES to allocate a greater proportion of research to biological control of weeds.
- Systematics: Congress could support education in IPM at the Land Grants; Congress could direct ARS to increase resources and staff slots for biosystematics labs working in biological control; More postdoctoral fellows in NBCI for taxonomic work (APHIS assure funds are available).

* Cook and Granados report:
  - Increase accountability through long-term interdisciplinary research on basic and applied problems.
  - Transfer of technology from the laboratory to the field must involve greater enhanced education system and stronger support of Extension.

Additional comments:

We must define what USDA can be realistically held accountable for. We don't want to be held accountable for things beyond our scope of responsibilities.

How do you measure individual performance, given that we do so much in teams? We must give credit where credit is due.

The USDA Economic Research Service has been involved in evaluating some BBTs. It would be an effective contributor to this area.

Breakout-Group Discussions of Accountability for Biological Control

Participants were divided into groups to discuss accountability in a biological control process. The following questions were posed to participants:

1. How can USDA strategically increase accountability for biological control policy, research, and delivery?
2. Specifically,
   * What are the areas where accountability could and should occur?
   * What are the areas where continuous feedback would be beneficial?
   * What are the most effective ways to bring in continuous feedback?
   * How can an increase in accountability be measured?

Representatives of each group later met to compile the ideas into a summary list. (A complete list of recommendations from each group is detailed in Appendix 5.) The summary list was presented to the entire group and modified as requested. The final synopsis follows:

SESSION III SYNOPSIS: Biological Control Accountability in USDA

To whom is USDA accountable for biological control?

- Customers - those who directly use services
- Beneficiaries - those whose well-being is enhanced by the services (including the environment)
- Stakeholders - organizations with an interest in the results (including government, environmental groups)
- Partners - those USDA works with
- Congress

Who in USDA needs to be accountable for biological control?

- Secretary of Agriculture - successful national programming / strategic planning
- ARS - research, implementation, evaluation, technology transfer
- APHIS - research, regulation, implementation, evaluation, technology transfer
- FS - research, implementation, evaluation, technology transfer
- CSREES - research, implementation, evaluation (including rural sociology), education, technology transfer
- Economic Research Service - economic evaluation

For what is USDA (and agencies) accountable?

- Control of pests in an environmentally safe manner

- Planning and prioritization of targets
- Research
- Regulation
- Implementation
- Evaluation (scientific, economic, sociological; project continuation and termination)
- Education
- Maintaining ethical standards and customer satisfaction
- Carrying out agency mission
- Fiscal responsibility
- Technology transfer

How will accountability be achieved?

- Apply Government Performance Review Act (GPRA) in all areas.
- Apply a program logic model: input-output-outcomes. Flexibility must be built into the system.
  1. Develop a systematic plan that includes goals, objectives, expected outcomes (definable measures for individuals and/or agencies) for national and local projects; allocate resources/authority to those individuals and/or agencies. Ensure legal compliance.
  2. Strong leadership from the proper Department-level coordinating body.
  3. Utilize no-year funding to ensure the Strategic Plan is implemented.
  4. Establish communication mechanisms and information repositories re: status of Strategic Plan implementation (e.g., annual report, WWW site, databases, agents imported, agents released, records of establishment, records of impact, etc.). Document and communicate scientific breakthroughs.
  5. Peer review.
  6. Inclusive policy-making process to ensure a knowledge-based process.
  7. Establish a more comprehensive project selection process, including peer review, feedback processes, regular evaluations, etc.

How to measure outcomes?

Quantitative measures (number of commodities affected, geographic distribution, agricultural profitability, producers and land managers implementing biological control technology, number of emerging [spin-off] businesses and products, reduction in target pest density, decreased pesticide use, number of grants received and amount of non-USDA resources contributed to USDA projects).

Qualitative measures (healthier ecosystem, increased trade, broader public acceptance for biological control, acceptance of biological control as a basis for pest management, advances in science, lack of adverse effects).

SESSION IV: Development of a Draft Plan for Coordination, Regulation, and Accountability of Biological Control in USDA

LARGE-GROUP DISCUSSION TO DEVELOP A USDA BIOLOGICAL CONTROL PLAN INCORPORATING COORDINATION, REGULATION, AND ACCOUNTABILITY

• Does APHIS plan to develop biological control regulations through its Consolidated Statutes? • APHIS has discussed this. They may be useful to use for biological control. • Instead of working with the Consolidated Statutes, let's look specifically at enabling legislation that can be attached to the Research Title of the Farm Bill. • Do we need enabling legislation? Would it be better to strengthen the consolidated Plant Pest Act? • We must have enabling legislation so biological control research doesn't get shut down by lawsuits. We're very vulnerable. Enabling legislation can provide a mechanism to resolve conflicts brought up by those challenges. • The Consolidated Statutes have been written without public input. We need a facilitative approach to consider all the people involved. • We need to explore all the approaches available and look for ways to strengthen biological control through the regulatory process. • Develop a committee to explore the options.

• Conflict of Interest concept: APHIS applies for permits AND grants permits. This creates a perceived conflict of interest. • We need a more formal separation of tiers of permitting and receiving. • How to deal with it? 1) APHIS changes the process, or 2) some oversight is provided to ensure the perception of fair treatment of everyone.

• APHIS' tracking system (WWW) for permits is excellent.

• The perspective of CSREES scientists at Land Grant Universities was presented by John Obrycki (Iowa State University) in the following written plan at the workshop:

A Center at the Department level is needed to facilitate and provide leadership for biological control.

* Because NBCI currently has the mission, and is widely supported by the scientific and environmental communities, NBCI is the logical choice to be this Center.
* The Center should be at the Department level so it answers to the Office of the Secretary, but may administratively be within a single agency.
* Positions (not people) provided from each affected USDA agency (ARS, APHIS, FS and CSREES)
* Functions: a) Promote, facilitate and provide leadership in biological control; b) Promote biological control through education at all levels (in the general public, grower groups, environmental groups, etc.); c) Attain appropriate policy authority for non-plant pests (natural enemies), using the "Strawman" as a process model; d) Champion increased support for biological control.

• IBC[3] charter can be used as a vehicle for the Center. • This body must be manned by people who make this their career -- dedicated full-time workers. • The concept of a unifying body and NBCI has its roots very early, so the current NBCI is part of that evolution. It has roots in many agencies to serve the broad needs of biological control. • This is an endorsement of what we discussed in the first workshop session on coordination. • You are proposing that NBCI be moved to the Secretary's office? • Yes. • In this model, NBCI would be comprised of many agency representatives. People would be assigned full-time. • There should be some coordination and/or relationship with the U.S. Department of Interior. • This Center must have full-time support people, as well as strong links to authority people in each agency. • USDA-APHIS-BATS could stay where it is and regulate, but should have a liaison with the Center.

• Is NBCI who we want? (It must be interagency, and recognized and given authority by different agencies.) • Whether or not we point at NBCI, it at least should be considered as a model because it has been so successful. • **We would like NBCI to be raised and recognized as a model for this coordinating body** [*by vote of the group*]. • We would like to see a place to help us deal with NEPA and other regulations. BATS won't do that with non-plant pests, so this is a group that could facilitate this as outlined in the philosophy of the "Strawman." • We accept the philosophy embodied in the "Strawman."

SUMMARY OF KEY POINTS

Hoped-for outcomes:

* Improved coordination at the national level. (Increased efficiency)
* Improved regulatory approach. (Predicatable timelines, predictable regulatory roadmap by organism type.)
* A systematic approach for planning biological control projects. (Acceleration of the safe release of biological control organisms; increased efficiency of the entire system.)

Additionally,

* Increased economic return on rangeland, forests, agricultural lands.
* Satisfied customers/stakeholders.
* Achieve economic benefits and get a return on USDA's investment.
* Improve human environment and health.
* Implementable alternatives to traditional management methods for farmers.
* Increased confidence in food safety.
* Increase awareness and understanding of natural biological processes.
* Allow scientists to do science and not get bogged down in the regulatory process.
* Accelerate the safe release of biological control agents to the field.
* Greater role of biological control in pest management in this country, including management of weeds, insects, nematodes, and plant diseases currently unmanaged; replacement of undesirable pest control methods with biological control.
* Ensure biological control is credible and safe.
* Ensure proper stewardship for federal money.
* Ensure compliance with environmental laws.

We need from Administrators:

* Commitment to do this.
* FTEs assigned to an operational coordinating body. FTEs must have adequate authority within their agencies.
* Empower a group to move forward to implement the proposal.

SESSION V: Presentation of Workshop Results

OVERALL PERCEPTIONS OF THE GROUP

The workshop was urgently needed because:

* Current USDA biological control (biological control) activities are highly fragmented;
* USDA biological control activities are less effective than they could/should be;
* The regulatory process has been unstable and has not met the needs of most customers;
* Many groups are spending unreasonable amounts of time on regulatory issues and still are not in legal compliance;
* Many customers have asked (for years) for improvements which have either not come or are coming too slowly; and
* Many proposed regulatory solutions have been inappropriate for the degree of risk involved.

Current biological control organization within and between Agencies is inefficient, lacking in programmatic continuity, many times misfocused, often falling short of full implementation, etc.

We are urgently in need of reinvention through modernization of the infrastructure and delivery system for biological control.

The group worked hard and well in support of a "Team USDA" solution.

Everyone at the workshop participated by speaking, listening and evaluating.

Improved regulations were thought to be a key to future success of biological control:

* Not just permitting through plant pest regulations.
* Biological control community and producers need a facilitated regulatory system.
* "One-stop shopping" for all regulatory issues is needed.
* Federal Plant Pest Act, NEPA, Endangered Species Act, Lacey Act, FIFRA, etc.
* Detailed discussion of regulatory issues to follow.
* Strong sense that the evaluation and approval system for exotic beneficial microbes (weed pathogens) needs the most improvement (APHIS and EPA issue).

Departmental-level coordination is felt to be essential by all:

* Needs to function somewhat like the USDA IPM Subcommittee.
* Has different needs than IPM, but would operate closely with the IPM Subcommittee.
* Needs to be operational in nature and have associated full-time staff contributed by all Agencies involved.
* Is needed to assist the Department with overall biological control philosophy, policies and functional plans.

The final outcome of the reinvention needs to:

* Provide an OVERALL SYSTEMATIC APPROACH for developing, regulating and implementing biological control, and interfacing biological control technologies with IPM programs.
* Ensure that accountability is built into the plan to measure effectiveness and continuously help improve the system.

Activities need to center on traditional biological control:

* Augmentation, conservation, introduction, and microbial biological control technologies.
* Continue to modernize through facilitating mechanisms to accommodate new biologically based technologies (BBTs) as they are developed.
* Work with the IPM Subcommittee to assist others in developing or using BBTs in IPM.

I. COORDINATION

* State Representatives formally proposed (and the group agreed) that a "Center" was needed at the Departmental level to promote, facilitate and provide leadership across all USDA Agencies conducting biological control. This is needed to ensure that an OVERALL SYSTEMATIC APPROACH is developed within USDA and is used to select, investigate, regulate, and implement biological control programs.

* The Center must use a facilitation model of operation, not dictatorial or command-and-control methods. The National Biological Control Institute was highlighted as an excellent example of how such a Center could be designed and operated. Such a Center would require dedicated staff positions and representation from all USDA agencies involved in biological control.

* The Center would be coordinated by a Director (appointment could be from any Agency) who would answer to the Deputy Secretary's Office as does Barry Jacobsen. However, ideas and programs are primarily solicited from customers, scientists, and agency representatives who would also serve as Advisory Group members.

* The Center will help pull together programs:
  - across groups with different Missions;
  - to attain one-stop regulatory shopping;
  - to promote biological control through education of the general public, producers, environmental groups, etc.;
  - to champion increased support for biological control.

* The Biological Control Center:
  - must have Department-level status;
  - must have some full-time staff;
  - must have active representation from all Agencies (APHIS, ARS, CSREES, ERS and FS) -- Agency representatives must have adequate authorization to influence programs;
  - must have mechanisms for formal input from customers.

* Some of the elements that need coordination across Agencies are:
  - program priority-setting, including line management and grant programs;
  - research programs;
  - field implementation;
  - regulations;
  - technology transfer;
  - solicitation of funds and program accountability.

* The Center must have linkage with and between other Departments and Agencies such as:
  - Environmental Protection Agency;
  - Department of Interior;
  - FWS, BLM, NPS, etc.; and
  - Other key groups including Customers.

II. REGULATIONS

A Facilitative Regulatory System developed with and for users and stakeholders is needed.

A. Fragmented System Currently
   1. No focal point
   2. No roadmap of compliance requirements
   3. No ability to handle different kinds of organisms including plant pests, non-plant pests, and pathogens.

B. We Need
   1. Leadership for the regulation of biological control organisms is needed to develop a regulatory system for this variety of organisms.
      a. Authority and accountability within the Department should be within APHIS or at a higher level.
      b. Should address not only permitting under existing authorities, but compliance under NEPA both in conjunction with permitting for organisms and for projects being implemented.
   2. Improved regulatory system
      a. Procedural - 10 points distilled from extensive customer input contained in the "Strawman" document can be used as a model
         - notification for interstate movement and release
         - quarantine and containment facilities
         - release of first-time introductions
         - commercialization
         - exclusions
         - conflict resolution process

         Supplement the current success with users of APHIS in getting a permit-tracking system on-line.
      b. The possibility of a *biological control regulation* under our existing authorities needs to be explored and developed.
         - Other models such as the biotechnology regulation should be evaluated.
      c. The *options for enabling legislation* need to be evaluated including the Consolidated Statutes; development of legislation under the Research Title of the Farm Bill; working with stakeholders to create a Biological Control Act.

3. Anticipation is needed of appropriate regulations and questions to be addressed.

C. Primary Goals for Regulation of Biological Control
   1. To protect U.S. agriculture, forests, human and animal health and the environment/ecosystems and to enhance trade.
   2. Ensure the public and agricultural community's confidence in a regulatory system for biological control
      a. Foster public support
      b. Facilitate and overcome obstacles for commercialization and research
   3. Facilitate timely implementation of biological control by satisfying legal requirements under various authorities including the PQA, FPPA, animal quarantine laws, NEPA, T&E, *Lacey Act*, FIFRA, and state laws.

D. Attributes of an Effective Regulatory System
   1. Consistent with and appropriate to the risk presented
      a. primarily to non-target organisms
      b. considers benefits
   2. Based on sound science
   3. Streamlined and efficient processes
   4. Predictable, consistent, without ad hoc decision-making
   5. Provides "one-stop shopping" for regulatory compliance across agencies.
      a. A roadmap for proceeding through the regulatory process
      b. NEPA is a major concern, although its implications extend beyond biological control

E. Barriers and Opportunities
   1. Unclear jurisdictions, inertia, no business processes, lack of acceptance, lack of scientific information.
   2. Coordination with the States, partnerships within the biological control community, facilitate biological control and provide customer service.

III. ACCOUNTABILITY

A. Currently, there is no uniform selection and development of projects
   1. In a way that ensures the delivery and a high probability of success within a predictable time frame.
   2. Accountability within USDA resides in several places:
      a. Secretary of Agriculture, APHIS, ARS, CSREES, ERS, FS.
      b. Research, Regulation, Implementation, Evaluation, Technology Transfer, Education, Methods Development and others.
      * This indicates an overlap of responsibilities: each of the agencies has its own role to play, depending on the program. There are a variety of customers and needs to be met.

B. A systematic way of selecting and prioritizing pests and projects is needed.
   1. GPRA - Customer Service
   2. Application of the program logic model would develop and deliver programs in a systematic manner with strong leadership and coordination across all the involved individuals and agencies.
      a. From discovery - research - development - technology transfer through implementation and delivery.
      b. Flexible system with planning done up front to assure success and compliance with legal requirements.
      c. With goals, objectives, and outcomes accounted for national and local projects;
         - appropriate allocation of resources; and
         - feedback mechanisms from inception through completion.
   3. To assure Accountability, we need to be able to evaluate. There are a variety of measures that can be put in place.
      a. Quantitative
         - Producers and land managers implementing biological control;
         - Increase in number of emerging biological control businesses;
         - Increase in non-USDA resources contributed;
         - Decreased pesticide use;
         - Increased agricultural profitability.
      b. Qualitative
         - Biological control accepted as a significant pest control technology;
         - Public acceptance;
         - Advances in science;
         - Healthier ecosystems.

IV. THE STATES' PERSPECTIVE ON USDA BIOLOGICAL CONTROL EFFORTS

A. We must protect American agriculture from harmful insects, weeds, and diseases.
   1. Accelerate development of cost-effective, environmentally safe alternatives to chemical pesticides.
   2. Biological control helps farmers and ranchers economically.

B. What needs to be done:
   1. Develop a smooth process for implementing biological control programs.
   2. Develop a facilitated regulatory process
      a. Streamlined
      b. Clearly written
      c. Sensible
      d. Regulations consistent with risk
   3. Develop a coordinated approach to biological control projects
      a. Planning
      b. Resource allocation
      c. Roles
      d. Time frames
      e. Accountability

C. Why does it need to be done?
   1. Current lack of coordination and leadership at the national level.
   2. Fragmentation of responsibilities among several USDA agencies and other Departments.
   3. Confusion delays the implementation of biological control programs.

D. How can it be done?
   1. Develop a USDA biological control philosophy
      a. Policies that reflect the philosophy
      b. Actions to implement the philosophy in a consistent, timely manner
   2. Establish a coordinating group (the Biological Control "Center") at the Deputy Secretary level.
      a. This level has authority over all the agencies represented at this workshop.
      b. Can serve as a champion of biological control at the national level.
      c. May facilitate biological control activities within USDA
      d. May serve as liaison with other agencies, universities, and states
      e. National Biological Control Institute serves as a model for such a coordinating group.
      f. Same level of staffing as NBCI, plus staff from ARS, CSREES, FS
      g. Empowered by the Secretary of Agriculture
   3. Create new biological control regulations
      a. Incorporate elements of the "Strawman" document
      b. Establish clear procedures that are responsive to customer needs
      c. Continue to protect American agriculture

E. Requests
   1. Make significant progress toward these goals by rapid placement of such a coordinating body.
   2. Establish a functioning coordinating body by the end of January 1997.

V. OUTCOMES OF IMPROVING COORDINATION, REGULATION AND ACCOUNTABILITY OF USDA BIOLOGICAL CONTROL

Short-term outcomes:

* A systematic and efficient biological control system from discovery, through regulation, to implementation and release.
* Greater role of biological control in integrated pest management systems, including management of weeds, insects, nematodes, and plant diseases currently not managed, and providing additional alternatives for pest control.
* Implementable alternatives to pesticides under regulatory review.
* Ensures that biological control is credible and safe.
* Acceleration of the safe release of biological control organisms into the field.
* Implementing a greater number of and more effective biological control agents for controlling pests in integrated systems.
* Increased stakeholder satisfaction with confidence in biological control and the biological control activities in the USDA.
* Ensures compliance with NEPA and other laws.
* Scientists conducting science instead of being bogged down in the regulatory process.
* Ensures proper stewardship of Federal dollars.

Long-term outcomes:

* Improved human and environmental health.

* Increased economic return and economic benefits for producers; achieve a greater return on U.S. investments.
* Increased public confidence in the safety of food.
* Reduction in economic and environmental loss from pests.

VI. NEEDS FROM THE USDA ADMINISTRATION

* Commitment to follow through with recommendations and proposed solutions.
* Assign FTEs and funds to the biological control coordinating body to enable its operation.
* Provide authority (from each agency) to the coordinating body.
* Empower a group to move forward in implementing the proposal.

VII. EXPECTATIONS

Within 90 days:

* Group is established to develop more specific recommendations for the formation of the coordinating body and a time frame under which it can be developed.
* Deputy Secretary and Agency Administrators review and endorse recommendations.
* Do it!

The above outline was used by the workshop reporting team [R. Carruthers (USDA-ARS), S. McCammon (USDA-APHIS), L. Bezark (CA Dept. of Food & Agriculture), and S. Rockey (USDA-CSREES)] to provide an oral report to USDA Agency Administrators at the end of the workshop.

The presentation was made at 10 a.m. Friday, Oct. 11, 1996, at the U.S. Department of Agriculture Jamie L. Whitten Federal Building in Washington, D.C. Senior agency personnel attending were: Floyd Horn, ARS Administrator; Ed Knipling, ARS Deputy Administrator; Dick Parry, Director, ARS Office of Technology Transfer; Terry Medley, APHIS Administrator; Ann Bartuska, Staff Director, Forest Health and Protection, Forest Service; Barbra Webber, Associate Deputy Chief for Research, Forest Service; Al Elder, Deputy Administrator, APHIS Plant Protection and Quarantine; and A.J. Dye, Assistant to the Administrator, CSREES.

SUMMARY DISCUSSION

Following the formal presentation of the results of the USDA Invitational Biological Control Workshop, discussion was opened to the audience which consisted of approximately 40 people who attended the workshop (representatives of ARS, APHIS, FS, CSREES, universities, state Departments of Agriculture), as well as senior Agency personnel.

The following statements represent a synopsis of the post-presentation commentary. Attempts have been made to represent the ideas of the speakers, if not the exact words.

John Obrycki, Iowa State University

IBC^3 and NBCI should together form the body of a new Departmental-level biological control coordinating council.

We recommend that APHIS withdraw the Advance Notice of Proposed Rulemaking and start over in a facilitated way with input from customers.

We are pleased with NBCI because they've coordinated and facilitated biological control activities involving many different people, agencies, and organizations.

Terry Medley, Administrator, USDA-APHIS

Accolades to the workshop participants for accomplishing a great deal and considering a comprehensive view of biological control. We must continue to think in terms of how biological control fits within integrated pest management (IPM). To be effective, we need knowledge, skills, and desire. We've had the knowledge and skills in biological control; now, through this workshop, we see the desire.

My advice: Identify outcomes and goals, be clear about activities and mandates. Don't get bogged down in procedures and means, or in prescribing a specific solution. Regulatory authority is a very difficult concept in terms of "one-stop shopping."

My concerns: Regarding establishing a new biological control coordinating group, are we looking at a new idea through old lenses? Can we establish, for example, a "virtual organization" - one team, with commitments from every agency? You can achieve your goals more quickly if you don't attempt to make structural changes.

I suggest you write a clear statement of goals, and options of how to get there. Your clarity of focus and objectives are very impressive. Build upon the desire that came out of this workshop, but don't get bogged down in procedures that would keep your goals from being achieved.

Ed Knipling, Deputy Administrator, USDA-ARS

Congratulations on your achievements in this workshop.

A similar proactive coordination resulted in the Departmental-level IPM Subcommittee. Could this biological control coordinating body fit under the IPM Subcommittee? The Department would endorse your group's goals and objectives, but there may be a hesitancy to create more Departmental-level groups.

Biological control perhaps hasn't had the right balance - we've been overbalanced on the discovery end, but we haven't followed through on delivery, scale-up, etc. Have we oversold biological control prematurely? This is excellent science, but we have a long way to go to transfer this technology.

I don't know whether a biological control coordinating body is most appropriate at the Deputy Secretary level. The "virtual organization" concept is worth looking at.

A.J. Dye, Assistant to the Administrator, USDA-CSREES

Why can't biological control fit into the IPM Subcommittee structure?

E.S. Delfosse, Director, USDA-APHIS National Biological Control Center

A biological control coordinating body needs to be operational, whereas the IPM Subcommittee is primarily a policy-level group. The biological control expertise required in the IPM Initiative is not high enough; the biological control component has been a minor part of this Initiative. Biological control needs to act independently. Many problems that involve delivery are specific to biological control.

Positioning a biological control coordinating group within the IPM Subcommittee wouldn't be supported by the customer group that attended this workshop. Historically, whenever biological control is subsumed into IPM, biological control dies. Biological control is not subservient to IPM. Biological control requires specific knowledge and tools. The states are very concerned that if biological control goes under IPM, the states' needs will not be met.

Ray Carruthers, USDA-ARS National Program Leader for Biological Control

Biological control should not come under the IPM Subcommittee. Biological control operations need to be coordinated across agencies and institutions; we need to maximize our resources. The national regulations are very specifically tied to biological control. I serve on the IPM Subcommittee which is a good group, but it operates at the policy level and is not operational.

This workshop group is not asking for more money; it's asking for an umbrella to help use current funds better. We want to use existing people. We want to develop connections and be empowered to use them. This group represents literally thousands of people involved in biological control across the nation.

We're not trying to overcome any other group, we just want to improve biological control operations so we can make impacts in pest management and transfer the technology. Our scientists are very dedicated: empower them and they'll work hard for reasonable programs and outcomes.

Obrycki

IPM is an outgrowth of biological control. Conceptually, the two are very different. From my experience, I know that it does not work to include biological control within IPM groups.

To establish a biological control coordinating body, we don't need to create anything new, we just need to better use the groups/means we already have, such as NBCI and IBC^3.

Barbra Mullin, Montana Department of Agriculture

Thanks to the USDA personnel who organized this workshop and who have included the needs and input of the state Departments of Agriculture in their deliberations.

I work with farmers and ranchers who have pests. We need something that works. Biological control has the potential to be an economically viable management tool that will control pests, especially

pests that lack any other practical control mechanism. Biological control is a valuable tool. But this effort must be organized at a national level. Montana has put lots of money into biological control; we rely on the national program. The IPM Subcommittee has good ideas, but it doesn't make anything happen. We need action. We need an *active* national biological control program.

Ann Bartuska, Staff Director, Forest Health and Protection, Forest Service

Accolades for the level of effort that went into this workshop. I'm really pleased that the Forest Service was acknowledged as a land management agency with an interest in biological control. We have made a commitment to the research, development and application of biological control methods.

I encourage this group to coordinate its work, make the connections among agencies, identify people who should play a role in this, and get on with it. Don't wait for a program that's highly structured.

Bob Nowierski, Montana State University

The unique attributes and needs of biological control warrant its separation from IPM. Don't merge biological control with IPM.

Cindie Fugere, North Dakota Department of Agriculture

I represent the Western Weed Coordinating Committee, a group of federal land managers and state Departments of Agriculture.

The government has a chief role to play in the development of biological control of pests for rangelands, which are lands that are worth very little economically. If you develop biological control agents, I will get people to use them on their land. This technology deserves elevated importance. No one else will develop biological control agents if you don't. We may be able to foster a cottage industry in biological control agents, but the federal government will still have an up-front role to play.

Thank you for responding to our needs.

Sally McCammon, USDA-APHIS

The workshop Steering Committee will put together a workshop proceedings and will deliver an executive summary to Administrators.

Knipling

I don't buy all the reasons why biological control should not go into the IPM Subcommittee. It would be a mistake to separate biological control from IPM - biological control could be the centerpiece. I think the Department would want to project an image that biological control is within IPM, although we know scientifically that it's not the same. We need to find some way to integrate them, but not diminish the operational aspect needed by biological control. Don't throw this idea out the window.

McCammon

We've started a dialogue. We need to develop recommendations.

Carruthers

We don't care what we call it, we just want to do something positive to coordinate biological control efforts.

Sally Rockey, USDA-CSREES

We must understand the urgency of this. Something new and different has to take place, our customers have said. There's an *urgency* about biological control. This is an opportunity to take some recommendations forward.

Obrycki

Your customers/stakeholders have made a request. We've discussed these issues for three days and come to a consensus. Putting biological control into IPM is not an acceptable alternative to your customers.

Ed King, USDA-ARS, Weslaco, TX

IPM as it is currently defined and used in the United States (particularly in rowcrops) often implies management with synthetic chemical insectides with biological control as a last resort. The biological control approach is a more preemptive type of paradigm. We want to put biological control way out in front of IPM so it can drive IPM. IPM and biological control are almost two different paradigms.

McCammon

There's a strategic importance in keeping biological control separate from IPM.

Nowierski

There are so many unique issues in biological control. If biological control is combined with IPM, will we be able to address these issues?

Carruthers

I don't know where this program idea will go, but it has been a very productive workshop. Good things will come out of your effort. I'll do all I can to make it functionally work in whatever form the program takes. We need to stick with it.

White Paper

Coordination, Regulation and Accountability of USDA Biological Control

A Backgrounder[1] Prepared by

E. Delfosse,[2] H. Browning,[3] A. Bullard,[4] R. Carruthers,[5] D. Heron,[2]
S. McCammon,[2] S. Rockey[3] and L. Wendel[2]

for the

Invitational Workshop on USDA Activities in Biological Control

8-10 October 1996
USDA Center at Riverside, Conference Rooms C & D,
4700 River Road, Riverdale, MD

and

11 October 1996
USDA Administration Building, Room 107A
Washington, DC

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1 This backgrounder is a summary of 12 key documents on biological control (see references) and some additional citations. Due to the summary nature of this White Paper and the very short time frame in which it was prepared, it does not necessarily represent the individual or combined perspectives of the writing team or their USDA agencies. Rather, it is an abstracted summary of points developed by other subject matter specialists over the past five years, and was produced only as a starting point for the Workshop.

2 Animal and Plant Health Inspection Service.

3 Cooperative State Research, Education and Extension Service.

4 Forest Service.

5 Agricultural Research Service.

EXECUTIVE SUMMARY

Biological control has been an accepted and effective method of pest management for over 100 years. Although USDA was a pioneer in developing and implementing biological control technology, the discovery and widespread use of chemical pesticides shifted emphasis away from biologically-based technologies (BBTs) in the 1940s. Several recent reports from the Office of Technology Assessment, the National Research Council of the National Academy of Sciences, and others have advised increased research and development of BBTs by USDA and others. In addition, several reports have identified elements of coordination, regulation and accountability that should be in place for a USDA biological control program to be highly successful.

At the request of the Deputy Secretary of Agriculture, Mr. Rominger, an inter-agency Steering Committee co-chaired by USDA-ARS and USDA-APHIS has been given the task of providing input to the Secretary's Office on methods to improve these elements within USDA's biological control program. The Steering Committee, under the oversight of the Secretary's Office, has organized an inter-agency workshop to address these critical issues, and to provide guidance to the workshop participants in producing a final report for Mr. Rominger's and USDA Agency Administrators' consideration.

The following *White Paper* is a consolidation of perspectives that were presented in 12 primary documents that the steering committee felt were of key importance to the future of biological control, supplemented with additional citations where appropriate (see references). This was not meant to be an exhaustive review or to replace any of the original documents, but was done to provide workshop participants with an overview of several key issues and recommendations that have been made within the last several years. This base is provided so that the *Invitational Workshop on USDA Activities in Biological Control* can build upon these issues rather than reinvent ideas that have already been formulated by previous workshops, expert panels, or individual specialists.

To briefly summarize, the *White Paper* states that increased communication and cooperation within and between USDA Agencies, customers, stakeholders and industrial partners on biological control is severely needed. Several methods to enhance these areas have been suggested, including the formation of a coordinating body that would interface with all appropriate USDA agencies, the USDA IPM Steering Committee, and critical customers, cooperators and stakeholders. The *White Paper* cites several options that were recommended by the Office of Technology Assessment in their recent comprehensive review of this subject matter. Actual quotes from this and other reports have been included in their original form even though they were directed to Congress or to other governing bodies.

In several reports and in the proceedings of several key meetings, lack of adequate biological control regulations has been considered one of the primary factors limiting the development and implementation of BBTs. The most frequently identified problems were the lack of stability in the regulatory system, inadequate science-based processes, uncoordinated programs between USDA-APHIS and EPA, and no conflict resolution process. The *White Paper* discusses the primary regulatory issues associated with biological control, links this discussion to potential risks as identified by an Audubon Society Study and others on host-specificity in biological control, discusses USDA-APHIS' past role in regulations, lists known gaps in the current regulatory system, presents a new set of guidelines for regulations and implementing procedures (the "Strawman"), considers the potential need for enabling biological control legislation, and announces the availability of APHIS' *Advance Notice of Proposed Rule-Making*.

In the final sections of the *White Paper*, suggestions to increase accountability, feedback and resource allocation within and between USDA agencies were discussed. These are clearly areas that have not been explored adequately in previous reports and thus warrant significant attention by Workshop attendees. Whereas the other areas of consideration need selection of appropriate options for implementation and fine tuning, new options need to be suggested by the group to best determine how to assess USDA effectiveness on delivering biological control technologies to producers and other customers. Agency Administrators and their staffs then need to work with the Secretary's Office to determine the best way to allocate resources with each of the agencies to accomplish the overall biological control goals of the Department.

INTRODUCTION

Globally, biological control has been an accepted method of pest management for over 100 years. It has been used traditionally in agriculture, forestry and rangeland areas and for medical and veterinary pests, but has great potential for management of other pests (e.g., in urban, interiorscape and environmental areas). Conservationists are "turning to biological control to help save biodiversity" (OTA 1995). In fact, public support for biological control as the preferred method of managing nonindigenous and indigenous pests is increasing in many countries (NAPPO 1994, OTA 1995, Leppla and Delfosse 1995), but is not without risks and challenges (Howarth 1991). However, the risks of population-level effects to non-target species from use of specific natural enemies in biological control programs are historically very low (Bennett 1990, Kauffman and Nechols 1992, OTA 1995, Wapshere *et al.* 1989).

There is tremendous potential for solving pest management problems for the public good through research, implementation and technology transfer of biological control. The United States Department of Agriculture (USDA), along with university, State and private partners, has played a major role in biological control for over 100 years. However, gaps have recently been pointed out in regulation, coordination and accountability of USDA biological control activities, that prevent this technology from being used to its maximum advantage.

In July 1996, the Deputy Secretary of Agriculture charged USDA with examining how appropriate regulation and increased coordination of biological control could increase delivery of research and implementation of biological control as part of integrated pest management (IPM). A Steering Committee was formed to convene a biological control workshop and provide recommendations to the Deputy Secretary. The Steering Committee is co-chaired by the Agricultural Research Service (ARS) and the Animal and Plant Health Inspection Service (APHIS), and involves the Forest Service (FS), the Cooperative State Research, Education and Extension Service (CSREES), and the National Biological Control Institute (NBCI).

As a basis for the biological control workshop, the Steering Committee assembled representative literature covering regulation and coordination of biological control (see references). Committee members were assigned review of specific documents, according to the following evaluation criteria:

(1) To increase (1a) coordination, (1b) cooperation, and (1c) facilitation of USDA biological control activities;
(2) To define a regulatory system that (2a) assures safety and (2b) facilitates the implementation of biological control;
(3) To increase (3a) specific accountability by agencies and (3b) to provide means for continuous feedback; and
(4) To develop a consistent USDA policy on biological control, involving (4a) allocating resources, (4b) marketing biological control, and (4c) educating customers and stakeholders, leading to an increase in support for biological control.

The remainder of this *White Paper* summarizes the reviews of the main papers prepared by Committee members, plus relevant comments from other papers. This document is intended as background information, to guide discussion at the *Invitational Workshop on USDA Activities in Biological Control.*

(1) To increase (1a) coordination, (1b) cooperation, and (1c) facilitation of USDA biological control activities.

Background

Many reports identified the lack of coordination, cooperation and facilitation of biological control as critical needs (Delfosse 1991, Ehler 1990, ESCOP 1989, Gabriel and Cook 1990, Granados *et al.* 1991, Leppla *et al.* 1995, Moran 1992, McDonald 1991, 1992, 1993, 1994, Metterhouse 1985, Mullin and Fugere 1996, OTA 1993, 1995, Tauber *et al.* 1985, Thomas 1987).

Several gaps clearly exist in coordination and cooperation in biological control. Among the most important are economic constraints (discussed below); it is difficult to coordinate biological control if key groups compete for a shrinking share of limited resources. "Lack of necessary coordination ... was the most prominent problem identified by every workshop and advisory panel" convened by OTA (1995), and earlier by the Experiment Station Committee on Organization and Policy (ESCOP 1989). Ehler (1990) pointed out that better coordination would increase potential for biological control success, and would reduce the costs and risks. It would also reduce duplication of effort. Leadership in coordination of biological control efforts is needed.

The need for increased coordination and cooperation is expressed in other ways. For example, there is concern over the lack of understanding of basic mechanisms of biological control (Cook and Granados 1991), and of the lack of quality control guidelines for the commercial sector. Coordination of efforts can help address these issues. Granados *et al.* (1991) suggested establishing "national research centers to develop biological control methods with local/cooperative, clearing houses for basic and applied information on and the delivery of biological control agents." Increased technology transfer of biological control is vital (Cook and Granados 1991), which can be facilitated by increased coordination.

The FS manages the 191.5 million acre National Forest System, in which it manages pests with a Forest Insect and Disease Research (FIDR) research program and a Forest Health Protection (FHP) pest suppression program. FIDR has not always been able to provide solutions needed by FHP, in part because "the research timetable does not always match the needed expediency for pest control" due to the long-term research needs (OTA 1995). FS has recently "begun to address problems with rangeland weeds on federal lands."

Federal research funds are administered by CSREES through the National Research Initiative (NRI), formula funds, and special grants to land grant universities via State Agricultural Experiment Stations. (CSREES was established as part of the *USDA Reorganization Act* of 1994, combining the Cooperative State Research Service, CSRS, with the Cooperative Extension Service, CES.) CSREES announced a biological control section of the NRI in 1994, with $2.5 million. Congress eliminated the CSREES line item for biological control in 1995, but NRI will continue to fund the program in 1996. Changes are anticipated for fiscal year 1997 (S. Rockey, personal communication, 1996).

ARS devotes over $100 million per year to biologically based pest control technologies, over half of which is tied to traditionally defined methods of conservation, classical, augmentative and microbial biological control. In FY 1996, over 180 scientist-years were spent on research in support of 279 traditional biological control-related projects. Coordination of these efforts within ARS is handled by the National Program Staff that has at least six different subject matter specialists in entomology, plant pathology and weed science. ARS projects are managed using a matrix approach to project development, and evaluation within individual projects is peer reviewed by both ARS and non-ARS scientists prior to implementation. Cooperative linkages with other agencies, stakeholders and customers are considered at the time of project initiation and through various program assessments and workshops throughout the tenure of each project. Additional

formal linkages with action agencies, customers, and cooperators could enhance ARS programs, increase technology transfer of research outcomes, and thus make ARS programs more effective.

The goal of the APHIS biological control programs is to implement biological control technologies to control pests of economic and environmental importance in cooperation with Federal and State agencies. The principal approach is to maximize the use of natural enemies. This involves the importation, quarantine screening, rearing, establishment and augmentative releases, redistribution, and evaluation of natural enemy impact on each project. The final goal of most projects is to develop, implement and/or transfer biological control technologies to cooperating State agencies. APHIS currently implements biological control programs against 10 arthropod pests (boll weevil, brown citrus aphid, cereal leaf beetle, Colorado potato beetle, Euonymus scale, gypsy moth, Japanese beetle, pine shoot beetle, Russian wheat aphid and the silverleaf whitefly); and five weed pests (purple loosestrife, common crupina, diffuse and spotted knapweed, and leafy spurge). The Plant Protection and Quarantine (PPQ) budget for biological control programs was $11.6 million in FY 1994, $10.0 million in FY 1995 and projected to be approximately $8.8 million in FY 1996. Three key PPQ laboratories solely involved in biological control programs are located at Niles, Michigan, Bozeman, Montana, and Mission, Texas. APHIS is also responsible for regulation of a large portion of biological control in the United States (Mendelsohn *et al.* 1993), and established and supports NBCI, a group established to "promote, facilitate and provide leadership for biological control."

A few other Federal agencies are involved in biological control. The U.S. Department of the Interior (DoI) has a very small biological control program, with only eight weed projects and an investment of $1 million. Some of these projects are conducted in cooperation with APHIS and ARS. The US Army Corps of Engineers has supported biological control of weeds activities since 1959. All are members of the Federal Interagency Committee for the Management of Noxious and Exotic Weeds, which also has membership from APHIS, ARS, CSREES and FS, plus other agencies. Increased cooperation between the State Agricultural Experiment Stations (SAES), ARS and APHIS is also warranted in foreign exploration and importation activities (Charudattan and Browning 1992).

OTA (1995) found that States provide matching research funds for SAES through CSREES, directly fund experiment stations and land grand universities, and operate quarantine and insect rearing facilities. Twenty-eight States have their own research and implementation programs for biological control. Twenty-two States have cooperative programs with APHIS and ARS, but there is little coordination among or between States and the Federal government. OTA (1995) concluded that "the harshest critics say that the necessary [biological control] coordination is virtually nonexistent today." OTA's interviews with scientists highlighted the worry that the "poor coordination of biological control programs among government agencies can result in replication of effort" and other problems. Increased coordination "would increase the potential for success and reduce the costs and risks." OTA (1995) stated that, despite the expenditure of over $130 million each year by 11 federal agencies, "this expenditure appears to be largely uncoordinated and to lack adequate prioritization." Implementation is less than ideal because "no federal research agency takes responsibility for this function." Past coordination activities have been unsuccessful "because the coordinating committees and institutes have had inadequate institutional status, authority, and funding." Noxious weeds are spreading up to 4,000 acres per day, and land managers favor biological control of weeds, but resources are not available for weeds, and "no federal research agency has yet made a large effort in this area."

Attempts at Biological Control Coordination

Experiment Station Committee on Organization and Policy

ESCOP, representing the State agricultural experiment stations of the land-grant university system, established a *Working Group on Biological Control* in 1985 and sponsored a national symposium, *New Directions in Biological Control*, in 1989. This group stated (ESCOP 1989)

> A coordinated, national scientific initiative is needed to maximize our understanding and use of biological control.... Because there is currently no formal organization to coordinate the efforts of university scientists, government agencies, and industry, these sectors have

> often developed independent and conflicting agendas. By coordinating efforts toward a common goal, we can minimize duplication, foster cooperation, and focus effort on important problems. Researchers should be included in the development of guidelines and regulations overseeing environmentally safe use of biological control agents.

National Biological Control Institute (NBCI)

In 1990, APHIS established NBCI following five years of internal discussion. NBCI has provided a degree of biological control coordination. For example, NBCI: initiated development of the *National Biological Control Information Center* (a combination of NBCI and the ARS *Biological Control Documentation Center* information activities); established a bulletin board system and the first *World Wide Web Internet Home Page* for biological control; completed limited funding initiatives discussed below; instituted a *Customer Advisory Group* with rotating 3-year terms that has involved 25 of the key biological control workers in the U.S. since 1990; and provided technical advice and coordination for many biological control and IPM programs; and other activities. Coordination from NBCI has been sought by other Federal agencies and international groups, and recently NBCI has been charged with preparing a strategic plan to coordinate APHIS' programs.

OTA (1995) emphasized that NBCI was "a response to a perceived need to increase the prominence of and coordinate biological control within APHIS, between APHIS and the other USDA agencies, and between APHIS and organizations outside the government." In 1992 APHIS elevated NBCI to the Office of the Administrator, the highest administrative position that biological control has ever reached in any country. NBCI's mission has remained to "promote, facilitate and provide leadership for biological control." However, by establishing NBCI, APHIS created "considerable institutional conflicts within USDA" OTA (1995). OTA found reviews of NBCI's impacts to be "mixed," and stated:

> NBCI is effective at outreach beyond the beltway and is highly respected by scientists in state government, universities and other institutions. However, the institute's highly regarded staff and expertise are not always paid attention to within APHIS. For example, efforts by [NBCI] to involve stakeholders in the development of biological control regulations were not incorporated into the broader proposed rule that APHIS issued for nonindigenous species. Moreover, the institute has not been incorporated into the working group representing various agencies in the USDA IPM Initiative. This oversight is unfortunate because it perpetuates the historical separation of biological control and IPM pest control disciplines.

Interagency Biological Control Coordinating Committee (IBC^3)

IBC^3 was established in 1990 by USDA. The purpose of IBC^3 was to increase interagency cooperation in developing and implementing biological control, recommending policy, developing a federal and state framework to achieve mutual goals in biological control, providing leadership in biological control within USDA, proposing uniform departmental policy in such matters, reviewing and coordinating biological control programs nationwide, developing joint funding initiatives and protocols, setting priorities for target pest selection, coordinating foreign exploration and collection, and reporting these activities to the USDA Agency Administrators.

In 1994, IBC^3 designed the *National Biological Control Program* (NBCP) that linked the existing infrastructure of the five USDA agencies and partner State institutions to mobilize limited resources to accelerate the development and implementation of biological control technologies. Additional funding of $20 million per year was requested to initiate this effort. The goal was to "improve the capacity for farmers, foresters, and homeowners to solve pest problems in ways that enhance the sustainability and competitiveness of American agriculture and forestry." OTA (1995) noted that IBC^3, unlike NBCI, "never had any direct funding."

Options for Biological Control Coordination

The visions of biological control coordination, cooperation and facilitation have yet to reach full inter-agency implementation. The ESCOP Biological Control Working Group has established linkages, raised visibility of biological control, provided budget inputs and planned workshops. The roles, responsibilities and organizational placement of NBCI are being re-examined. Federal agencies received minimal funding from the *NBCP*. IBC^3 no longer meets due to lack of funding and agency commitment to this effort.

Thus, although considerable groundwork has been laid over a decade for biological control coordination in the United States; the needs, issues and challenges have been discussed widely at many meetings and in the literature; and there is generally strong support for the effort from the States, the private sector, scientific and environmental communities, appropriate political support, funding and organizational placement for national biological control coordination and cooperation is yet to be realized.

OTA pointed out that both NBCI and IBC^3 were designed to increase coordination of biological control, but "neither fulfills it perfectly - the institute because it is located within an operations agency and lacks funds and authority; the committee because it has largely ceased to function." OTA (1995) suggested five options for Congress to improve biological control coordination:

Option. *Congress could select either the NBCI, IBC3, or a new unit (perhaps incorporating both organizations) as the institutional site for national coordination of biological control. Selection of NBCI would requite its elevation to a higher level within USDA, because its current position makes it accountable to the priorities of one agency (APHIS). Selection of IBC3 would require revitalizing the now inactive committee. Specific coordinating responsibilities and appropriations would need to be assigned to whatever organization is selected.*

Option. *Alternatively, Congress could create a centralized agency responsible for all federal activities related to biological control. This option seems only remotely feasible today, because biological control programs are dispersed throughout at least eight agencies, in many cases related directly to their pest control responsibilities.*

Option. *Congress could strengthen and stabilize the new biological control program within the National Research Initiative, and also make provisions so that CSREES could fund some projects of long duration rather than the five-year grants the agency says are mandated by current law. Note that the National Research Initiative program on biological control has not received strong support from the current Congress and might be eliminated in fiscal year 1996.*

Option. *Should Congress choose to fund the USDA IPM Initiative, it could stipulate that the designated organization for coordinating biological control be a participant. Even without designating a coordinating organization, Congress could require that the NBCI be involved in the Initiative to help integrate biological control and IPM programs (see also chapter 3 for discussion of problems related to a lack of coordination between biological control and IPM).*

Option. *Congress could direct USDA to maintain a consistent and comprehensive database on biological control introductions. Several different institutional sites might be possible. Previous attempts at developing such a database in the ARS suffered from erratic support. The history of poor documentation and recordkeeping by the APHIS regulatory unit that permits biological control introductions (see chapter 4) makes it seem an equally problematic site at this time; although whatever data are developed by APHIS via the permitting process should be incorporated into the biological control database. Other possibilities include the National Agricultural Library or the National Germplasm Program. Development of a biological control database could occur even if no coordinating structure for biological control is designated.*

OTA (1995) noted that a major problem was that "National goal-setting mechanisms lack funding authority and therefore have little direct influence over the research agenda." This results in a scattered effort, with the consequence "that some of the research components necessary to enable the practical uses of [biologically

based technologies] BBTs are not addressed." And "it is clear that not enough attention has been given to the essential research to take BBTs out of the hands of scientists and into those of farmers and other users." OTA also highlighted that "Despite clear-cut institutional responsibilities, ARS has not always delivered solutions that are field-ready to APHIS; as a result, APHIS has developed its own research capabilities...."

Facilitation of development of commercial biological control is hindered by lack of access to information about BBTs that are ready for technology transfer, according to OTA; four options were offered (note that the OTA references to ARS in the following options refer equally well to all federally funded research programs across agencies):

Option. *Congress could instruct ARS to make all discoveries related to development and commercialization of certain BBTs public property (i.e., not allow ARS scientists to patent their discoveries). Areas of particular significance to industry are the development of artificial diets for natural enemies and of new pheromone formulations. The ARS scientists involved might need additional incentives to continue research in these areas. This approach would not be desirable for microbial pesticides, however, because larger companies view the licensing arrangement as vital protection of intellectual property.*

Option. *Congress could instruct ARS to encourage the development of CRADAs even with companies that cannot provide funding for the research. The agency would need to provide internal incentives and support for scientists that engaged in such projects.*

Option. *Through its oversight functions, Congress could encourage ARS to communicate discoveries of relevant technologies and opportunities for collaborative ventures more effectively to all members of the BBT industry. Better communication, perhaps via joint conferences or meetings, might have the additional benefit of better informing ARS scientists of the potential end uses of their discoveries (see chapter 5).*

Option. *Congress created [IR-4] to support research that develops data for registration of minor use pesticides. Since the scope of IR-4 was expanded in 1982 to cover "biorational" pesticides, only a small part of the program's funding has gone towards work on BBTs (see chapter 5). Congress could specify that a larger portion of the IR-4 program funds should be designated to help meet the data requirements for registration of microbial pesticides and pheromone-based products.*

(2) To define a regulatory system that (2a) assures safety and (2b) facilitates the implementation of biological control

Background

The need for reasonable regulations and procedures to provide oversight for importation, interstate movement and release to the environment of biological control agents has been identified for many years by several independent groups in the United States (Charudattan and Browning 1992, Cook and Granados 1991, Coulson *et al.* 1991, Glenister 1991, Granados *et al.* 1991, Marrone and Sandmeier 1991, Mullin and Fugere 1996, National Research Council 1996, OTA 1995, Shantharam and Foudlin 1991, Tolin 1991). Regulations should be strategic in nature; science-based, consistent, easily understood and transparent; effective, responsive, flexible and dynamic; and should meet domestic and international needs (Medley and McCammon 1995). A conflict-resolution procedure is needed, and leadership is essential to involve all partners early in discussions of programs and agents to ensure that resources are not committed to programs that are unlikely to be implemented (Delfosse 1996). Agency responsibilities need to be established, and fixed times for regulatory decisions should be established (OTA 1995). A regulatory roadmap is needed; "if you don't know where you are going, any road will take you there" (Below 1987). "A sound, but scientifically sensible, regulatory system is essential for making biological control work" (Tolin 1991).

There was a strong view that biological control agents should be regulated differently from chemical pesticides; in particular, regulations and procedures should be product-oriented, rather than process-oriented, and there should be a shift from a chemical paradigm back to a biological paradigm (Chabot 1991, Cook and Granados 1991, Glenister 1991). Separate registration packages for each strain or strain combination will not work for future needs. The overlapping responsibilities of APHIS (under the *Federal Plant Pest Act*, FPPA) and the EPA (under the *Federal Insecticide, Fungicide and Rodenticide Act*; FIFRA) "pose unnecessary barriers to registration of biological-control [sic] organisms."

Regulations that facilitate interstate movement of biological control agents are also needed. The private sector considers federal regulation of the natural enemy-producing industry "to be among their greatest challenges and wish to participate in the development of any new rules" (OTA 1995). Clear, consistent and concise regulations for field testing and registration of commercial biological control agents are needed (Granados *et al.* 1991, Marrone and Sandmeier 1991). State legislation should be consistent with federal regulation (Marrone and Sandmeier 1991).

Risk and Biological Control

Many groups have addressed risk in biological control (Cate and Maddox 1994, Charudattan and Browning 1992, Coulson and Soper 1989, Granados *et al.* 1991, Howarth 1991, McDonald 1993, Osburn and Nicholas 1992, OTA 1995, Shantharan and Foudlin 1991, Wapshere *et al.* 1989). Biological control is not risk-free, and it is not a panacea, but regulation of biological control agents should be in proportion to the risk they present in possibly causing *population-level effects* on non-target species. Most reviewers concluded that the main risk from biological control is the *potential* of non-target damage, but that there are few recent examples where this has been documented. Clouding the issue is the paucity of studies that specifically look for non-target effects.

OTA (1995) pointed out that BBTs have low risks compared to conventional pesticides, but do have risks that should be examined by long-term, post-release monitoring, and that there are also important economic and environmental risks from *failure* to control pests. Thus, not providing cost-effective BBTs due to over-regulation must be avoided.

Charudattan and Browning (1992) and Dunn and Martin (1993) stressed the importance and need to promote the dialogue regarding critical issues affecting research, development and implementation of biological control. Increased and continual dialogue between regulators, biological control researchers, and environmental groups is required throughout the entire regulatory process. Scientists have technical expertise to contribute to the regulatory process and are concerned about safety issues; they should be directly involved in regulatory actions.

Risk-benefit analyses should be used when appropriate in pre-decisional analyses (Dunn and Martin 1993). Unfortunately, it appears the more we know about an organism under regulatory scrutiny, the higher the presumed risk (Charudattan and Browning 1992). The risks inherent in biological control are not properly taken into account by current regulations (Cate and Maddox 1994), and risks from biological control and biotechnology are often inappropriately linked (Shantharam and Foudlin 1991). This linkage tends to overestimate the risks due to introduction of unmodified agents, and can raise unreasonable fears of the potential for biological control agents to produce *population-level effects* on non-target species. This can lead to over-regulation and under-use of biological control.

Risk assessments should include components of risks from continuing the use of alternatives (e.g., chemical pesticides), which are well known and documented. The presumption of maximum risk may represent a legal safety net, but it is not consistent with more than 100 years of biological control history in the United States (Charudattan and Browning 1992).

Releases of exotic arthropod parasites and predators of arthropod pests seldom represent a significant threat to endangered species or other non-target organisms because: (1) emphasis is generally placed on rather host-specific natural enemies to begin with; (2) generalist natural enemies usually have poor searching abilities and tend to feed preferentially on whatever is abundant; and (3) density-dependent processes nearly

always preclude significant attack rates at low host/prey densities (such as those likely to occur in the case of rare or endangered species). Probably the most important cause of animal extinction is habitat destruction. It seems more likely that extinction or endangerment of a non-target species would occur because of interspecific competition with an exotic invader (consider salt cedar) or pesticide treatments used to suppress it, than by a natural enemy that needs it as host or prey to survive.

Legner (1986) and Coulson and Soper (1989) reviewed the risks associated with biological control, and concluded: (1) arthropod parasites and predators of insects and other arthropods present the lowest environmental risk of all categories of biological control agents; and (2) as a consequence of biological control programs, over 600 insect parasites and predators have been imported into the continental United States, of which more than 200 have become established. Of these, only two species (both hymenopterous secondary parasites introduced in the early 1900s when biological control was in its infancy) are believed to have had detrimental effects, and these are of little importance. Current protocols would not allow for the introduction of such species.

Regulation of biological control requires different types of information and understanding than that for chemical pesticides. For example, biological control agents employ a series of steps to locate and affect their hosts. If the sequence is disrupted, the agent typically does not accept the host for sustenance or reproduction. Habitat is another factor that affects the interaction of agents and potential host targets. If a potential non-target host is located in areas (habitats) where natural enemies do not exist (spatial or temporal separation) no attack can occur. This is important as laboratory (physiological) host range studies do not typically take such factors into consideration. Regulations must allow biological control practitioners to evaluate host-specificity using both physiological and ecological characters.

Host-specificity is seldom an all-or-nothing phenomenon. Thus, attack of a host without reproduction of the natural enemy will cause little harm. The ultimate question is what will be the ecological host range leading to a population level impact on a non-target species be in the field environment? To that end, the Audubon Society promotes increased monitoring of biological control agents following field release. They state (Cate and Maddox 1994), "There is virtually no evidence of harmful outcomes from scientifically conducted biological control projects, but there is also little information available, and the consensus is that monitoring should be part of most projects." In addition, they suggest monitoring some of the 1,000 species of non-indigenous organisms established in the United States since European colonization to see how host ranges may have evolved.

Evaluation of risk associated with biological control is more complicated than using the standard **risk = (hazard x exposure)** formula, particularly for biological agents that can establish and spread. Generalist agents that affect many species, however, clearly pose more risk than host-specific agents. McDonald (1993) cited the role of familiarity and knowledge in shaping perceptions of potential risks and benefits. Risk-based decisions, however, are necessary and some risk is acceptable. Attempts to estimate risk and assess benefits should be scientifically-based and should use existing data bases even independent of actual host range testing. Known phylogenetic, ecological, and biological relationships are often quite indicative of the host range of related groups and can be used to help estimate risk of a potential non-indigenous biological control agent.

Proper use of biological control agents is a bona fide concern. However, Audubon states (Cate and Maddox 1994) "There are concerns that existing regulatory statutes for control of plant pests (particularly agricultural crop pests) are inappropriate for effective oversight of agents used to control non-plant pests." Regulatory oversight needs to be consistent with scientific advances, guidelines need to be developed that reflect the scientific nature and biological fundamentals of host-specificity, all biological control agents should be systematically regulated (not some by EPA, some by APHIS, and others not at all). The process should exclude unsafe products and practices while not stifling others unnecessarily. USDA-APHIS currently promotes, conducts, and regulates biological control, which is an obvious conflict-of-interest that the Audubon Society would like corrected (Cate and Maddox 1994). They feel that EPA and USDA should initiate a comprehensive review of biological control regulations with respect to statutory authority. In either case, they believe that neither Agency will have adequate resources to hire the necessary specialists to

implement a science-based regulatory process, and thus recommend a peer reviewed process using knowledgeable specialists from a diversity of State and Federal institutions.

The cost of the regulatory process should also be restricted as high costs push biological control technologies into the commercial realm and towards agents with broad host ranges and large commercial markets. Narrow host ranges and many diverse markets may actually be the areas within which biological control agents may be most useful and effective. Whatever regulatory path is selected, it should result in fewer rejections of safe organisms and more disapprovals of deleterious agents.

Finally, a process by which regulators are accessible to customers is needed. Agencies need to define responsibilities for organism groups, define criteria and characteristics for risks and benefits, establish fixed times for regulatory decisions, facilitate access to procedures, and establish a voluntary mechanism to share results of safety testing (Granados *et al.* 1991). Osburn and Nicholas (1992) stated (referring to animal biotechnology) that the public should be represented, and access and participation in debate should be improved. Further, they suggested the following mechanisms for improving access: "1. Legislation regarding public participation in regulations decisions across the board; 2. Publication beyond the *Federal Register*; 3. Improved representation in decision-making processes; 4. Open forums; 5. Research on opening up scientific decision-making processes; and 6. Rebuilding public trust and regulatory transparency." These points apply equally to regulation of biological control.

In summary, all groups expressing a view (researchers, the private sector, environmentalists, regulators, etc.) agree that proper oversight of biological control is essential. These groups even agree in principle on the essential elements of a regulatory system for biological control: science-based, strategic, open, significant public involvement, transparency, flexible, dynamic, and responsive to national and international needs. However, as Australia discovered a decade ago, the challenge is in negotiating the details of the process (Cullen and Delfosse 1985), but the outcome of having reasonable regulations and procedures that enable and facilitate use of biological control agents is well worth the effort (Delfosse 1992 *a,b*). Such negotiations continue in the United States, and progress is being made (Delfosse 1996).

The Role of APHIS in Biological Control Regulation

OTA (1995) spent a large amount of time discussing APHIS' role in regulation of biological control. They concluded that APHIS' past regulation of biological control was "inconsistent and incomplete," or "uneven;" the review of applications for entomophagous agents "has been particularly lax;" and the current biological control regulatory system in APHIS "has a number of important flaws" such as lacking "balance, transparency, and efficiency." OTA stated that APHIS needs to "devise a regulatory framework that ensures environmental safety while encouraging the development and use of BBTs." A well-designed system would "screen out the greater risks from BBTs while facilitating adoption of the vast majority of these technologies." A tiered testing system could streamline data requirements, and requires developing a risk hierarchy. This is difficult, but the extremes could be determined: high risk would include use of most terrestrial vertebrates and generalist predators and plant-attackers; low risk would include host- or habitat-specific parasites, diseases and predators. Risk-benefit analyses should be used to address this issue, and host-specificity testing should be based on science (such as the centrifugal phylogenetic testing procedure, or the relatedness testing procedure). In particular, regulators need to be aware of the difference between the ecological and the physiological host range of biological control agents, and should regulate biological control agents in proportion to the risk they present to causing population-level effects on non-target species. The APHIS TAG has done a good job to the extent of their charge, but this group needs to be updated and expanded.

OTA (1995) stated that APHIS was aware of the need to update its biological control regulations and procedures when it established NBCI. In January 1992, APHIS Administrator Melland formally charged NBCI with reviewing how APHIS regulates biological control. Terms of reference (Mendelsohn *et al.* 1993) were to:

1. Examine APHIS' biological control regulatory authority, policies and philosophies;
2. Clarify biological control responsibilities of APHIS units;

3. Document the current biological control regulatory system used by the Biological Assessment and Taxonomic Support (BATS) group in the Plant Protection and Quarantine unit;
4. Consult widely with APHIS' customers about the current regulatory system (including implementing guidelines), and suggest a new system (now known as the "Strawman") based on this customer input and using the best available science; and
5. Propose a mechanism to facilitate APHIS' continued involvement with customers to ensure that the regulations and implementing procedures and guidelines are changed as science and societal needs change.

Referring to the *APHIS Biological Control Philosophy*, Administrator Melland stated, "In support of this philosophy, APHIS will develop regulations that facilitate the release of safe biological control agents, while maintaining adequate protection for American agriculture and the environment. The regulations will give clear and appropriate guidance to permit applicants, including specific types of data needed for review and environmental analysis and specific time limits for Agency review. They will be updated as the science progresses."

OTA (1995) suggested three options for Congress with regard to biological control regulation:

Option. *Congress could, through its oversight functions, instruct APHIS to streamline its permitting process and to design a more balanced regulatory system for biological control. Components of these changes might include the following:*

- *Developing a more even-handed regulation for biological control with broader input from all stakeholders (researchers, natural enemies companies, farmers and other users, wildland managers, state agencies, conservation biologists, etc.).*
- *Formulating an explicit policy concerning the regulation of nematodes. Although formally within APHIS's jurisdiction, nematode products rarely go through APHIS review. The agency needs to carefully consider whether this leaves any significant risk issues unaddressed. Potential impacts on companies producing nematode-based products must weigh into the development of a more formal policy.*
- *Instituting a technical advisory group (TAG) to evaluate proposed introductions of unprecedented biological control agents targeted at insect pests (entomophagous agents), and improving the science underlying the regulatory decisionmaking for these agents by developing appropriate host-specificity testing protocols. The different standards of review for biological control agents targeting plant and insect pests are based on historical concerns about agricultural crop protection and ignore our scientific understanding of the importance of native biodiversity and the value to agriculture of conserving native natural enemies. Enhanced review of entomophagous species may provoke objection from entomologists who are not used to this level of scrutiny.*
- *Developing mechanisms through which to include input from a cross section of nongovernmental organizations, including those concerned with environmental risk and conservation issues, in APHIS's decisions about biological control agents. The Federal Advisory Committee Act allows membership on advisory committee by nonfederal agencies so long as the committees adhere to certain procedural requirements. If APHIS chooses not to expand TAG membership, other channels may be available for nonfederal input.*
- *Requiring post-release monitoring of the non-target impacts from the highest risk introductions as a condition of the permitting process. The challenge is to develop a mechanism for funding such research, so as not to place undue burdens on a low-profit industry that produces a valuable set of low-risk pest control tools.*
- *Maintaining clearer records of permitted releases, the basis for these decisions, and any subsequent impacts, to improve future decisionmaking. According to APHIS, some of these changes are already in progress; these efforts deserve support and encouragement.*
- *Convening a panel of scientific experts to evaluate APHIS's past regulatory precedents as a basis for future permitting decisions. This review could help APHIS identify some of the high-risk releases and facilitate agency streamlining of other permitting activities.*

Option. *An opportunity to address some of the flaws in APHIS's regulatory system may present itself in the agency's efforts to consolidate all of its plant protection statutes into a single package.*

Option. *Congress could pass a new law embracing uses of natural enemies and microbial pesticides that would give more similar coverage to these two categories, but OTA does not find sufficient justification for this option. EPA, FDA, and APHIS all have expertise in different areas, which corresponds at least roughly with their current regulatory responsibilities. It is important, for example, that EPA continue toxicity studies on certain microbial products; the other agencies are unequipped to take over that function. Certainly regulatory gaps exist, but these can be addressed within the current institutional framework (see previous options).*

Quality and purity of commercial biological control agents was raised as a concern by OTA (1995), who made the following recommendation:

Option. *The quality and purity of natural enemies products is thought to vary. Some scientists have suggested that APHIS should regulate this area to improve the consistency of product performance. However, APHIS currently lacks jurisdiction to issue such standards. Industry organizations such as the Association of Natural Bio-Control Producers and the International Organization for Biological Control, and the industry is moving toward voluntary standards. Congress could instruct APHIS to work with the natural enemies industry to develop such standards and to future assist in these efforts by providing access to the scientific resources of USDA.*

Markets for BBTs could be increased by the following option (OTA 1995):

Option. *Congress could provide market opportunities for the natural enemies industry by contracting out the production of biological control agents used in federal pest control programs conducted by APHIS and the land management agencies. These agents are currently produced by federal laboratories.*

The NBCI-Facilitated "Strawman"

The outcome of the process of working with customers on needs in biological control regulation, involving attending over 300 meetings and presenting over 200 invited talks on biological control regulations over a four-year period, was the NBCI-facilitated "Strawman," which discussed the ten areas of most concern to APHIS' biological control customers (Delfosse 1996).

The "Strawman" is apparently the first scientific document placed on the Internet for peer review. Comments virtually unanimously supported the new procedures in the "Strawman" (a few reviewers liked the processes suggested, but thought they could be more strict in some areas). A coalition of eight Western States considered the "Strawman" at a biological control of weeds regulatory summit in April 1996, and concluded (Mullin and Fugere 1996) "We support [the "Strawman"] with minor modifications, as a guiding document for biological control of weeds regulation in the United States." The Working Group on Biological Control of Weeds of the Nearctic Regional Section of the International Organization for Biological Control (IOBC) also supported the "Strawman" at a meeting in Billings, Montana, on 26 July 1996.

Relevant Excerpts of the "Strawman" As it Relates to Definition of Regulatory Structure

The goals of this customer-driven process were to: (1) develop a conceptual model of biological control regulation; (2) prepare a draft of a new system based on this model (the "Strawman" in this document); (3) seek wide peer review of the "Strawman;" and (4) modify the "Strawman" after peer review and present APHIS with a series of suggestions of how customers wanted to see biological control regulated. NBCI developed a conceptual model of biological control regulation that incorporated the best aspects of suggestions made by customers. This model also incorporates the best applicable aspects of regulatory systems used in other countries, but is placed in the legal and administrative context of the United States. The "Strawman" discussed below has been prepared from this conceptual model.

Key Areas for Improvement Cited by Customers

Biological control regulation in the United States is based on a patchwork of laws (*Federal Insecticide, Fungicide, and Rodenticide Act* (FIFRA) of 1972-authority from the EPA; *Federal Plant Pest Act* [FPPA] of 1957; *National Environmental Policy Act* [NEPA] of 1970; *Plant Quarantine Act* [PQA] of 1912; *Federal Noxious Weed Act* of 1974; etc.) never meant to be used to regulate biological control agents. Regulation of biological control agents by APHIS based on these laws has not been updated significantly for over twenty years. Customers felt that the process tended to be subjective, inconsistent, not always based on the best available science, lacking leadership, inadequately documented, and in need of updating (OTA 1995). It was felt that APHIS' extremely dedicated BATS staff spent too much time on repetitive actions dealing with precedented biological control agents (see below), rather than concentrating on assessing risk presented by new (unprecedented) agents, and that risk assessment should be used more.

Customers concluded that the science of biological control, as well as commercial and environmental interests, progressed faster than the ability of the regulatory system to cope with needed changes. Also, new requirements under NEPA were thought to be unclear. Strong support was expressed by customers to work with APHIS to update the FPPA, to eliminate the use of 'indirect plant pest' as it applies to biological control agents, to accommodate biological control specifically, and particularly to revise APHIS' internal procedures and guidelines. They stressed that the updated procedures should be based on science, and decisions should be made in a risk assessment context. Customers also asked to be more involved by reviewing drafts of new procedures before final decisions are made.

Customers recommended that new or modified regulations, procedures and guidelines should have a "sunset period" (i.e., should be in place for no more than five years), after which a customer-oriented workshop should be held to evaluate the process and suggest revisions. An open protocol was also needed to help resolve conflicts-of-interest.

Modifications to the FPPA

Customers suggested strongly and often that APHIS might not have the authority to regulate all types of biological control agents. For example, many think that it is clear that APHIS has the authority to regulate plant pests and organisms that present a plant pest risk (e.g., phytophagous organisms and plant pathogens), but do not accept that APHIS has authority to regulate non-plant pests or organisms that do not present a significant plant pest risk (e.g., parasitoids, predators, insect pathogens, competitors, or antagonists). Customers further stated that unless the vague and standardless "indirect plant pest damage" legal clause in the FPPA is invoked, it is not clear that APHIS' authority extends to organisms that do not damage plants directly. This was the issue most often disputed by customers.

Based on recent handling of biological control regulations, customers thought that it would be a mistake to legislate changes to the FPPA resulting in an expansion of APHIS' authority, and that this could be counterproductive by limiting APHIS' future options and by restricting implementation of biological control. In fact, customers recommended making the minimum number of changes to the FPPA (and basing the changes on science; few outside APHIS equate "natural enemies" with "indirect plant pests") and making significant and sweeping changes to APHIS' implementing procedures and guidelines. In fact, customers suggested making changes to the implementing procedures an guidelines even if no changes are made to the FPPA. These changes would reduce the regulatory burden on BATS and on APHIS' biological control customers.

Based on customer input, it was clear that the addition of only three definitions to the FPPA could significantly improve the law. By making these adjustments, beneficial biological control agents could be separated from listed plant pests from which APHIS has the responsibility to protect American agriculture.

Definitions

Addition of three new definitions (beneficial organism, precedented organism, and notification) to the FPPA would take into account the long and overwhelmingly safe history of use of most biological control agents,

and would also provide the dichotomy between true plant pests and beneficial biological control agents that is now missing in the FPPA. These simple changes would go a long way to clarifying APHIS' regulatory authority for non-plant pests, and would place biological control agents in the proper context. Customers consistently emphasized that the definitions must be based on science, not on convenient (but non-scientific) legal terminology. In particular, "indirect plant pest" would no longer be used in conjunction with biological control agents, replaced by science-based definitions and a regulatory dichotomy of plant pest vs. non-plant pest.

Notification for Importation from Non-U.S. Sources, and Interstate Movement of Precedented and Unprecedented Organisms

Customers requested that APHIS should change the way it handles importation and interstate movement of precedented and unprecedented organisms. The goals are to lessen the administrative burden, to achieve reasonable levels of identity and purity, and to facilitate importation and interstate movement of safe biological control agents. This process can be facilitated by APHIS encouraging electronic notification, by providing special shipping labels that will be recognized by inspectors who can then facilitate rapid clearance of the shipment, and by providing guidance to inspectors in the form of specific instructions that emphasize the need for recognizing and facilitating movement of shipments containing live biological control agents.

The criteria proposed for importation and interstate movement by notification are that: (1) the identify of the organism must be made by a person who is qualified to make the identification; and (2) the organisms must be identified and must be sent as a pure colony/culture. (A "pure colony" is one free of living plant pests listed by APHIS, but not necessarily of symbionts or parasites that are difficult to detect, or not necessary to eliminate from a colony/culture. Also, it was suggested that host material sent with shipments of agents either cannot reproduce or is autoclaved in containment.)

Based on the long history of safe importation and interstate movement of biological control agents, and on a desire to lessen the administrative burden imposed on the community, customers suggested that APHIS could discontinue the requirement that States must provide concurrences for importation and interstate movement of biological control agents to approved facilities. APHIS would have the option of acknowledging the notification and forwarding a copy of the notification to the State into which the organism was/will be moved.

USDA Approval of Quarantine and Containment Facilities

If a system of notification for importation and interstate movement of an organism is adopted, there must be scientifically-valid and measurable standards in place which give a high level of assurance that a facility can prevent the organism from escaping. Customers stated that construction standards must be developed in collaboration with State and Federal quarantine managers and other knowledgeable customers, and then published by APHIS. SOPs must be in place that assure containment of organisms approved for each facility. Customers proposed changes in the philosophy by which USDA approves quarantine introductions, moving from the current organism-based system to a facility-based system.

Customers suggested that it is not necessary for each individual organisms that is proposed for importation or interstate movement to be approved on a case-by-case basis. The preferred alternative is that each facility should be inspected by USDA periodically to determine the specific kind, type or size of organism that it can safely contain. The hazard potential is also considered in this evaluation. Once a facility is approved, and an appropriate SOP is in place, all organisms requiring containment security up to the level of approval of the facility should be able to be imported or moved to that facility by the notification process discussed above. For example, after a facility is approved for containment of rust fungi, then importation or movement to that facility of all rust fungi and all organisms requiring a similar or lower level of containment (e.g., arthropods) should be allowed by notification to APHIS.

Regardless of the adequacy of the building, customers emphasized that the SOP and appropriate training and supervision of staff were the key elements in maintaining a safe quarantine or containment facility. The long global history of safe containment of biological control agents in poor facilities is an example of the importance of SOPs and committed staff.

Notification for Release Into the Environment of Precedented Organisms

Customers acknowledged that APHIS has gained considerable experience in regulating biological control agents. One result of this experience is the finding that introductions of many types of biological control agents can be conducted with little or no plant pest or environmental risk, provided that certain criteria and performance standards are met. APHIS should acknowledge that evaluation of biological control agents has developed tremendously from its beginnings over 100 years ago, and that this evaluation is based on careful observation of the interactions among thousands of host-natural enemy relationships in their home ranges, under laboratory screening, and in new environments following release. While customers acknowledged that post-release evaluation is often the weakest component of the biological control process in the United States, in many cases sufficient data have been gathered globally to be able to draw valid inferences about risk. Norms, protocols and practices have evolved that are adequate and appropriate to identify, evaluate and judge potential risk to non-target species posed by precedented biological control agents.

Customers proposed risk-based standards for additional releases of a precedented organism: the organism cannot have produced documented non-target effects that resulted in a catastrophic and likely permanent lowering of a population of a non-target species, or other significant quantifiable damage to a non-target species at the population level. This suggests a proactive, science-based evaluation.

Data Requirements

Data required for notification of release of precedented organisms should be brief and focused on the need for APHIS and States to track releases of imported organisms and their potential non-target effects.

Commercial Biological Control Agents

APHIS' customers believe that a straightforward process is required to facilitate importation, interstate movement and release into the environment of commercial biological control agents. The industry stated that most of these are precedented organisms that have been released globally for many years with no documented population-level effects on non-target species. Without a clearly articulated process, the industry will avoid research and development in biological control. Also, very low-risk agents will be subject to inappropriate continual regulation, and thus the potential for public and private sector benefit will be less than the potential.

A standard is necessary to facilitate direct field release of commercial biological control agents, regardless of whether they are produced in the United States or are imported from producers outside the United States. Commercial customers proposed that "product control" (i.e., assurances that the identity of the organism is correct and that listed plant pests are not disseminated as a result of the shipment) should be the goal, not "process control" (i.e., not regulation of the facility or the processes used in the facility to produce the product). Similar standards for reference are in place for items such as cut flowers or bulbs that are imported from overseas.

Release Into the Environment of Unprecedented Organisms

APHIS' customers believe that the degree of regulation of a biological control agent should be in proportion to the degree of risk to populations of non-target species presented by the agent, and that the regulatory process must be based on the best available science. For biological control agents there is a clear hierarchy of decreasing plant pest risk from plant-feeding/attacking organisms to non-plant-feeding/attacking organisms. However, there are many shades of gray within these broad categories, and the situation only becomes clear when sufficient information is available.

Customers proposed that the most of APHIS' effort in regulating biological control should be spent on examining the risks associated with release of unprecedented organisms, and further, that this be accomplished collaboratively.

For example, APHIS should provide customers with specific data requirements for *Environmental Assessments* (EAs) for the first release of an unprecedented organism. Customers suggested that the standards should be peer-reviewed, published in a scientific journal, and made available on the Internet and in paper copy. APHIS should encourage customers to prepare draft EAs, or help write EAs when requested to do so, and then should facilitate the review of the draft EAs by a representative group of knowledgeable customers. All customer groups repeatedly expressed willingness to participate in an open review process.

Customers emphasized often and vigorously that the process for examining the risk presented by an unprecedented organism should be by a two-tiered system: plant feeders (including, for brevity, species such as plant pathogens that technically do not "feed" on plants) and non-plant-feeders. The main difference in the data required for these groups is that host-specificity testing would be required for plant-feeders, but would be optional for non-plant-feeders. Threatened and endangered (T&E) species which may be affected by plant-feeders would be identified and tested when sensible to do so.

Many customers requested that APHIS should develop and distribute specific data requirements to determine if a new organism is a plant pest or presents a plant pest risk. Environmental, research and industry perspectives should be represented in development of these categories. Customers stated that, unless an organism presents a real, quantifiable, significant plant pest risk (i.e., attacks plants, or presents a quantifiable and significant risk of impacts to non-target species), it should not be regulated by APHIS unless the changes to the FPPA suggested above are approved. A customer should be able to petition APHIS to evaluate submitted data to determine the plant pest status of a particular organism. If APHIS determines that an organism is not a plant pest or does not present a significant plant pest risk, the petition would be granted, allowing unrestricted introduction of the organism. This should be done in a manner that satisfies all NEPA requirements for all agencies. Thus, the status of many non-plant-feeding organisms, antagonists and competitors could be determined much more quickly than at present, with no significant additional risk to populations of non-target species.

A goal should also be to lessen any unnecessary regulatory burden on APHIS from repetitive review of unprecedented organisms that have only trivial differences from precedented organisms, by establishing a framework using "similarity" and "functional equivalency" standards for examining unprecedented organisms.

Finally, customers suggested that APHIS should use benefit:cost ratios, when available, as additional factors in determining risk of unprecedented organisms. Theoretically, a higher degree of risk could be accepted for an unprecedented agent that is proposed for release against a pest that causes severe economic impact against a crop, or severe environmental damage against a valued native species, particularly if there are no other management options, or if existing management options pose similar or greater risk. Note that no scale is implied: a biological control agent for a cotton or corn pest would not always be of "high benefit" and an agent for a small cash crop, ornamental or weed would not always be "low benefit." Benefit:cost ratios should be determined when possible, regardless of the value of the affected resource.

Also, customers stated that unprecedented organisms should be imported or moved interstate to USDA-approved facilities by notification, but release into the environment of an unprecedented organism requires careful evaluation of plant pest risk and risk to populations of non-target species.

There was strong feeling that APHIS should become the facilitator of the review process for unprecedented biological control agents. One important role in this regard is interagency liaison, which should not be left to the customer. Customers suggested that a facilitating role for APHIS should be to initiate early contact with the DoI, Fish & Wildlife Service (FWS) to identify and help resolve any issues that arise with regard to T&E species. This is particularly important for T&E species that may be non-target species of a biological control agent by virtue of being closely related biologically to the target or by occupying an ecologically similar habitat. Early contact with other relevant agencies (e.g., EPA and the Food and Drug Administration) could

save years of delay by identifying and resolving the issues important to the other groups. For example, APHIS could facilitate agreement with FWS on host-specificity test lists for plant-feeding organisms that are suggested by an applicant.

Customers stated that certain biological control agents should be exempt from the APHIS regulations. Exemptions of classes of biological control agents may be initiated by APHIS or pursuant to request from customers. As part of developing a facilitating process, where biological control agents also qualify for "categorical exclusion" from the NEPA process, customers thought that all necessary procedural steps (see generally 40 C.F.R. 1508.4) to achieve that status should be taken by APHIS, and that all precedented organisms that meet the "no documented damage at the population level" standard, and all biological control agents indigenous to the United States, be excluded from regulatory oversight. Finally, customers suggested that NBCI should sponsor a workshop or other mechanism to determine the starting list of beneficial organisms to be excluded from further regulation.

Conflict Resolution Procedure

Conflicts arise in biological control due to the choice of target species or choice of biological control agent. Conflicts also can be set off by APHIS denying a permit for importation, interstate movement, or release into the environment. If a conflict arises, customers suggested the following resolution procedure:

1. Define the problem
2. Assemble a conflict resolution resource package
3. Impanel an ad hoc review group
4. Prepare a draft recommendation
5. Announce a final decision
6. Implementation

Enabling Legislation for Biological Control

Customers emphasize that biological control is regulated in the United States under a series of laws created for other purposes and that these laws don't meet the needs of the public or regulatory agencies. A new law, similar to the *Australian Biological Control Act* 1984, has been suggested, that would enable and protect biological control.

Miller and Aplet (1993) correctly point out that there is currently no federal statute that requires that biological control agents be reviewed before release, and that "existing federal regulations of biological controls is obscure and fragmented." They state that the review process considers economically valuable species but ignores "harm to non-economic species and to ecosystem integrity;" focuses on organisms rather than ecosystems, which allows repeated application in new habitats; largely ignores movement of indigenous natural enemies; and lacks requirements for post-release evaluation.

Also, after reviewing the three types of statutes now in place (quarantine acts to exclude unwanted organisms, registration acts for approving desirable organisms, and protective acts for preserving endangered species), the authors conclude that there is an inadequate regulatory framework for biological control in the United States. They then reviewed the *Australian Biological Control Act*, which they feel offers a "partial model" for the USA. They state positive aspects of the Australian Act as providing a procedural framework for discussion; limiting liability after agent approval; and approval for release in Australia only occurring after a decision that the agent "would not cause any significant harm to any person or to the environment."

Miller and Aplet (1993) propose a new federal statute, the *Biological Control Act*, which would implement a public review process for all biological control applications, emphasizing an ecosystem orientation, and acknowledging that biological control agents do not recognize borders between States and countries. The new law would also create a *Division of Biological Control* within USDA or EPA to oversee the process, provide coordination, maintain a biological control database and library, and generally serve as a

"clearinghouse" for biological control information (this point is relevant to review criterion [1]). States should also consider similar legislation, although it is unclear how this would operate.

At a recent TAG meeting, it was discussed that a new biological control law would be beneficial as it could provide balance or possibly even precedence over T&E species issues if benefit:risk analyses suggest that a challenged project should proceed. Currently, USDA programs can be totally blocked by implementation of the *Threatened and Endangered Species Act*, regardless of potential positive benefits.

Customer Service

President Clinton has instructed APHIS and other agencies to provide improved service to customers at lower costs (e.g., *Executive Orders* 12862 of 11 September 1993 and 12866 of 30 September 1993). Customers consistently requested that APHIS make available a list of precedented organisms; allow for easy notification of movement of precedented biological control agents; develop a new process to facilitate the needs of the commercial sector; adopt a science-based, two-tiered process to evaluate unprecedented agents; establish a process for peer review; encouraging customers to prepare draft EAs; provide a *User's Guide*; meet frequently with customers to improve the process; etc.

The *APHIS Biological Control Philosophy* commits the agency to a consultative process that places biological control as the first option for pest management where it is appropriate, and to adjusting regulations and implementing procedures with customers as science advances and information and experience are gained. This commitment requires APHIS to communicate current guidelines and procedures to customers, and to seek input continually to adjust them appropriately.

The NRC (1996) report on ecologically based pest management (EBPM) suggested similar ideas as contained in the "Strawman." In particular, they proposed that evaluation of risks associated with deployment of biological control organisms and products should be based on evidence relative to both the type of organism or product and its method of deployment. The criteria need to be flexible to meet varying risk situations. All experience including that gained from the natural occurrence of the biological materials and their toxicity and field testing should be fully considered in regulatory review of new organisms or products. Prioritization of oversight should be established on the basis of the anticipated scale of use of biological materials and the persistence of the biological control organisms. NRC (1966) also suggested that FIFRA and FPPA pose unnecessary barriers to registration of biological control organisms, and that there should be guidance from EPA and USDA on risk criteria, data requirements and oversight of biological control organisms or products.

The APHIS Proposed Rule

APHIS published a *Proposed Rule* entitled *Introduction of Nonindigenous Organisms* on 26 January 1995 (60FR 5288-5307, Docket No. 93-026-1). On 16 June 1995 APHIS withdrew the *Proposed Rule* (60 Fr 31647, Docket No. 93-026-4) following receipt of 252 public comments, all of which were opposed to the *Proposed Rule* as written. OTA was critical of the lack of any provisions for post-release monitoring in the proposed rule, stating that this "suggests a possible reluctance by APHIS to confront the impacts of its permitting activities," and was "clear evidence that APHIS has not yet succeeded in assigning priorities and addressing ... risks."

The APHIS Advance Notice of Proposed Rule-Making (ANPR)

APHIS has published an ANPR (CFR 61:189, 50767-70), which was distributed to attendees prior to the USDA Workshop. The ANPR addresses inadequacies in plant pest regulations with regard to providing a means of screening organisms prior to introduction to determine the potential plant pest risks they may present, and covers many aspects of regulation suggested in the "Strawman" and by OTA (1995).

(3) To increase (3a) specific accountability by agencies and (3b) to provide means for continuous feedback.

Background

There have been many suggestions by authors cited above of increased accountability by USDA agencies in biological control regulation and implementation. Mullin and Fugere (1996) also suggested that the membership of TAG should be expanded, and TAG should review all proposed projects. In the *APHIS Biological Control Philosophy*, Administrator Melland stated, "APHIS believes that public input on procedures to approve the release of biological control agents is a desirable and necessary step, and will strive to gather input from scientists, industry, and the public." Mullin and Fugere (1996) suggested creating a clearinghouse for new projects so they can be announced before explorations and to cover unprecedented releases. This approach would enable interested parties to comment and could also alert possible funding cooperators. It was suggested that ARS *Documentation Center* compile information and pass to NBCI for dissemination. These authors also suggested that appropriate States should be notified by APHIS of releases of precedented species and proposed releases be publicized for comment, that a programmatic Environmental Impact Statement should be prepared by all USDA agencies, to which EAs could be tiered, and that EAs should include benefits and risks.

NRC (1996) recommended that coordinated multidisciplinary and interdisciplinary research was needed to develop and implement EBPM, with public oversight to help evaluate risks associated with biological control organisms.

Options Suggested to Increase Accountability and Feedback to USDA Agencies

OTA (1995) suggested that increased financial accountability was needed, and proposed the following options (note that the references to ARS in the following options refer equally well to all federally funded research programs across Agencies):

Option. *Congress could increase the accountability of ARS to the operations and land management agencies by designating funds within these agencies for pass-through to ARS for meeting their operational needs. Because new funding is unlikely in the current fiscal climate, these funds would have to be derived from the current budgets of these agencies.*

Option. *Congress could direct the ARS to allocate a proportion of its BBT funds to a targeted competitive grants program within the agency. These funds would be available for collaborative research projects that provide the follow through into field applications. Evaluation of the needs of farmers or other users at the inception of the research and of ways in which the BBT would meet this need would be essential to ensure real-world applicability. The size of this effort would need to be balanced against its potential effects on the agency's capability to conduct longer-term studies.*

OTA emphasized that proper "recordkeeping and monitoring systems" are needed to advance knowledge, improve development of new BBTs and allow development of a "tighter match between risks and regulatory testing requirements." OTA specifically highlighted the relative lack of biological weed control and post-release monitoring, and suggested two options:

Option. *Congress could direct the ARS and CSREES to allocate a greater proportion of their research funding toward control of weeds.*

Option. *Congress could direct all federal agencies that conduct or fund biological control programs to initiate or fund monitoring projects, especially for higher risk categories (see chapter 4 for discussion of risk categories). One way this might be accomplished is to give higher priority to research projects that include a monitoring component.*

Lack of incorporation of BBTs into IPM programs and disappearing systematic expertise were highlighted by OTA (1995) as obstacles to implementation of biological control. They suggested three options in this area:

Option. *Congress could support education in IPM through the Land Grant University system. Various approaches might be possible, for example, funding graduate fellowships in IPM.*

Option. *Congress could direct the ARS to increase resources and staff slots allocated to the Biosystematics Laboratory for work related to biological control.*

Option. *Postdoctoral fellowships from APHIS's NBCI have been used successfully to support U.S. taxonomic work. Congress could direct APHIS to allocate a larger share of its biological control funding for this purpose.*

Cook and Granados (1991) suggested that accountability could be increased through long-term, interdisciplinary research on basic and applied problems; transfer of technology from the laboratory to the field must involve greater enhanced educational system and stronger support of the extension system; and overcoming the economics of producing a product for control of a single disease or pest which discourages companies from investing the capital necessary to produce, formulate, register, and market such a product.

The areas of accountability and feedback to USDA agencies have not been adequately explored in previous reports and thus warrant significant attention by Workshop attendees. Whereas the other areas of consideration need selection of appropriate options for implementation and fine tuning, new options need to be brainstormed by the group to best determine how to assess USDA effectiveness on delivering biological control technologies to States, producers and other customers. Agency Administrators and their staffs then need to work together and with the Secretary's Office to determine how best to allocate resources with each of the Agencies to accomplish the overall biological control goals of the Department and to more effectively link biological control activities with existing IPM operations.

(4) To develop a consistent USDA policy on biological control, involving (4a) allocating resources, (4b) marketing biological control, and (4c) educating customers and stakeholders, leading to an increase in support for biological control.

(4a) Allocating resources

OTA (1995) identified at least 11 Federal agencies involved in biological control, with an annual expenditure of over $210 million, and highlighted their overlapping activities in regulations, research, funding, implementation, education and technology transfer. In addition, the States spend abut $90 million each year on BBTs. An estimate of public sector funding for biological control in the United States is given in Table 1; 1988-96 average annual Federal expenditure was $146.1 million; State expenditure in 1994 was $9.2 million.

Five priority funding areas have been identified: research; implementation; evaluation; meetings; and particularly, systematics. Granados *et al.* (1991) suggested that biological control should be funded as an activity for the "public good" by a tax on pesticides. Inadequate core funding, staff positions, and funding for mass-rearing, distribution and evaluation also limit biological control.

OTA (1995) concluded that strategies not considered biological control by traditionally trained biological control workers (such as the sterile insect technique, plant breeding, use of transgenic natural enemies, cultural control, etc.) are increasingly lumped with biological control and called "biologically-based pest management" or "ecologically-based pest management," which may divert funds that formerly were applied

to traditionally defined biological control. Approximately 50% of the resources reported by ARS currently fund traditional biological control research, and the other 50% fund other BBTs.

Thus, public sector funding for biological control is significant, but "appears to be largely uncoordinated and to lack adequate prioritization" (OTA 1995). Private sector investment in augmentative biological control has decreased, due in part to "the regulatory climate" (Tolin 1991). It is clear that additional focus of available funding for biological control is needed, and that partnerships (Federal, State, local, private sector and international) need to be formed to make the best use of resources.

NBCI is addressing the need for providing increased and focused funds for biological control in several ways. Following consultation with customers to determine their needs, a peer-reviewed, small grants program was established in 1990, in collaboration with other Federal and State agencies. The program was coordinated in particular with other funding bodies, to ensure that it was synergistic with their programs, and would leverage resources and begin to fill some of the gaps identified by customers. A summary of the NBCI small grants program is presented in Table 2.

Table 1. Funding (in millions of US dollars) for biological control in the United States (updated from OTA 1995, Table 5-1 and Figure 5-2).

Group	1988	1989	1990	1991	1992	1993	1994	1995	1996	**TOTAL**	**Average**
FEDERAL[1]											
USDA											
ARS	82	80	82	87	101	98	104	104	104	842	93.56
CSREES	30	37	40	36	37	39	41	43	44	347	38.55
APHIS	3	4	6	7	8	10	12	10	10	70	7.78
FS	3	5	4	5	5	5	5	5	-	37	4.63
EPA	-	-	-	-	-	1	1	1	0	3	0.75
ACoE	0.9	0.8	1.3	1.2	1.4	1.5	1.4	1.4	0	9.9	1.10
DoI	-	-	-	1	1	1	1	1	1	6	1.0
Subtotal	119	126.8	133	137	153	156	165.4	165.4	159	1,314.9	146.1
STATES[2]	-	-	-	-	-	-	9.2	9.2	9.2	27.6	9.2
TOTAL	119	126.8	133	137	153	156	174.6	174.6	168.2	1,342.43	156.54
Adjusted[3]	110	112	112	113	124	125	137.04	136.17	131.18	1,047.10	122.10

[1] USDA= U.S. Department of Agriculture; ARS= Agricultural Research Service; APHIS= Animal and Plant Health Inspection Service; CSREES= Cooperatives States Research, Education and Extension Service; FS= Forest Service; EPA= Environmental Protection Agency; ACoE= U.S. Army Corps of Engineers; DoI= Department of Interior.

[2] 28 States have biological control programs: AZ, CA, CO, CT, FL, HI, ID, IN, KS, MD, MI, MN, MO, MT, NC, ND, NE, NJ, NV, NY, OR, RI, SD, TX, UT, VA, WA, and WI. OTA state figures were for 1994 only; we assumed for this analysis that state funding of biological control was stable for 1994-96.

[3] Adjusted by OTA on the producer price index (PPI). In base year 1992 the PPI was 1.00; in 1995-96, it was estimated to be 0.78.

Table 2. Summary of the NBCI small grants program, 1991-6 (amounts in USD).

Type of Grant	Number	Amount	Average
Development of databases	8	$ 184,352	$ 23,044
Education and information	10	193,894	19,389
Implementation projects	47	679,829	14,464
Focus groups and workshops	4	25,700	6,425
Mentoring and staff development	7	86,770	12,396
Meetings	26	135,419	5,208
NBCI Postdoctoral Fellowships in Systematics (2-year grants)	5	373,952	74,790
Publications	22	165,229	7,510
TOTAL	129	$ 1,845,145	$ 14,403

Several gaps in implementing biological control were identified by customers, including economic constraints, particularly very limited core funding, staff positions, and funding for mass-rearing, distribution and evaluation. Concern was expressed over the lack of understanding of basic mechanisms of biological control, and of the lack of quality control guidelines for the commercial sector. Many of the NBCI grants (Table 2) were designed to begin to meet some the these needs, raise the visibility of biological control, and to leverage resources in other groups. The *NBCI Postdoctoral Fellowships in Systematics* is particularly important in biological control, understanding biological diversity, ecology, and training students, etc. OTA found that NSF and NIH also provide a small amount of resources for BBTs, and the CSREES-ARS IR-4 funds a small amount of research on biorationals. EPA contributes about $2 million annually to CSREES for training of pesticide applicators.

Options for Developing a Consistent USDA Resource Allocation Policy on Biological Control

OTA suggested the following options for Congress:

Option. *Proposed research funding for fiscal year 1996 provided through CSREES under the USDA IPM Initiative has taken this approach to ensure "buy in" by researchers, farmers, and others involved in all phases of the development and implementation of IPM programs (see box 5-1). Congress could fund this research initiative. Its potential influence on BBT research is unclear, however, because the role of BBTs in the IPM Initiative has not been explicitly stated. Hence, funding of the research component of the IPM Initiative would affect BBTs only if Congress instructed USDA to identify the role of BBTs or to allocate a proportion of the program for IPM research that incorporates biologically based approaches (i.e., bio-intensive IPM).*

Option. *Alternatively, Congress could allocate to the operations and land management agencies "redeemable credits" toward research that targets their needs by the USDA research agencies. These credits would obligate the research agencies to conduct a specified amount of research to meet the needs of the operations and land management agencies, but no exchange of funds would occur (i.e., funds would remain in the research agencies.) The research agencies would have to be informed, during their appropriations processes, of their obligations, and some tracking mechanism might be necessary to assure accountability for conducting the work and producing results according to the agreed priorities.*

Option. *Congress could improve the match between ongoing research and the needs of farmers by requiring research agencies to seek input from farmers and other users into funding decisions. For example, representatives of user groups, commodity groups, etc., could sit on funding panels or make recommendations to the Deputy Administrator of the National Program Staff of the ARS.*

Option. *Congress could create a competitive grants program specifically targeted toward BBTs that are well researched but not yet in practical use. The goal would be to invest in bringing research discoveries that currently lie unused into the field, particularly those of high technical merit but likely to yield profits too low to be of commercial interest. Such funds might be administered through CSREES, perhaps as part of its extension functions. Although new money would be required to set up the program, it would be very cost-effective, because only technologies on the verge of application would be funded. The*

same type of targeted funding mechanism currently underlies the Cooperative Research and Development Agreements under which private-sector companies invest in government research (see also chapter 6 for further options related to CRADAs). However, those agreements primarily address research that is amenable to commercial development.

(4b) Marketing biological control

Background

Despite the long list of major articles published over the past decade (including the OTA and NRC reports; see references), there is a strong perception of an "overall lack of advocacy to get biological control on the national agenda" (Granados *et al.* 1991) and of a major need to ensure that biological control becomes the strategy of first consideration in IPM. Obviously, pesticides can be valuable IPM tools when used properly. Too often, however, biological control is only considered after a pest becomes very widespread and other management strategies have failed or produced an inadequate level of control. NRC (1996) suggests biological control as the primary strategy to be used to manage pests with more intensive and environmentally costly alternatives applied only when BBTs do not adequately solve the problem. Others have made recommendations to establish national centers to supply information about biological control and demonstrate the efficacy of BBTs (e.g., Granados *et al.* 1991) and to establish a national program to promote and fund biological control as a "public good."

One of the most serious concerns raised was that biological control has no national advocate and is sometimes portrayed as out-of-date, while other strategies (particularly chemical control) have extremely vocal advocates and lobbyists, and is presented as "cutting-edge."

The "lack of leadership" of biological control and the lack of visibility of biological control are also cited as problems (Chabot 1991, Granados et al. 1991). Leadership is needed, for example, to provide philosophical support for developing appropriate biological control regulations. Customers, stakeholders and beneficiaries of biological control products are often not identified, and strategic plans and coordination among agencies can be improved.

However, by the early 1990s several groups had made significant policy changes supporting biological control and IPM suggesting that the interest and potential to develop and implement a coordinated biological control program still exists:

- In a 1993 press release, the Clinton Administration announced a goal of "reducing the risks to people and the environment that are associated with pesticides while ensuring the availability of cost-effective pest management tools for agriculture and other pesticides users. We will intensify our effort to reduce the use of higher-risk pesticides and to promote integrated pest management, including biological and cultural control systems and other sustainable agricultural practices, under the leadership of the USDA" (USDA 1993). This statement led to the USDA IPM Initiative, leading to a goal of "... development of IPM programs and implementation strategies for 75% of acreage within 7 years ...". A comprehensive set of regulatory and programmatic initiatives accompanied this change in philosophy which are being developed.

- The Department of Defense (DoD) produced "pest management measures of merit" (DoD 1994) that require "100 percent of all DoD installations [to] have pest management plans" in place by the end of fiscal year (FY) 1997; a reduction of "50% from the FY 93 baseline" of pesticide used by the end of FY 2000, and to ensure proper certification of "100 percent of all DoD installation pesticide applicators" by FY 1998.

- In a 1995 memorandum to the Deputy Secretary of Agriculture, the ARS Administrator announced intentions to redirect approximately $15 million of existing weed science resources into research in support of integrated management of exotic, invasive weeds and stated, "ARS believes, in concert with technical experts in land management agencies, that biological control is the best long-term economically feasible and environmentally safe approach to controlling invasive exotic weeds." Specifically,

enhancement of ARS activities for foreign exploration for biological control agents, evaluation of these agents for introduction, cooperative program development, and a commitment to work with APHIS on improved regulatory procedures were mentioned.

- FS and DoI announced major policy changes to "ecosystem management" in 1992-93.

- FS established a *National Center for Forest Health Management* in 1993, then in 1995 combined the *Center* with two other laboratories in an "Enterprise Team" to address forest health issues. Like NBCI, the FS Enterprise Team has an external board of customers that advises on policy and programmatic issues.

- CSREES announced a biological control section of the NRI in 1994, with $2.5 million (S. Rockey, personal communication, 1996). Congress eliminated the CSREES line item for biological control in 1995. NRI will continue to fund the program in 1996. Changes are anticipated for fiscal year 1997.

- Bruce Babbitt (Secretary of DoI) announced science-based changes in forestry management (Babbitt 1995), emphasizing "Science is not the problem. Science is what has made this country work. Indeed, only science - applied, interdisciplinary science - will let us realize our vision."

- APHIS approved a *Biological Control Philosophy* (USDA, APHIS, 1992): "APHIS believes that modern biological control, appropriately applied and monitored, is an environmentally safe and desirable form of long-term management of pest species. It is neither a panacea nor a solution for all pest problems. APHIS believes that biological control is preferable when applicable; however, we also recognize that biological control has limited application to emergency eradication programs. Whenever possible, biological control should replace chemical control as the base strategy for integrated pest management. In support of this philosophy, APHIS will develop regulations that facilitate the release of safe biological control agents, while maintaining adequate protection for American agriculture and the environment. The regulations will give clear and appropriate guidance to permit applicants, including specific types of data needed for review and environmental analysis and specific time limits for Agency review. They will be updated as the science progresses. APHIS believes that public input on procedures to approve the release of biological control agents is a desirable and necessary step, and will strive to gather input from scientists, industry, and the public."

- The *APHIS Biological Control Philosophy* was distributed globally, and discussed at dozens of national and international meetings. In 1994 the North American Plant Projection Organization (consisting of representatives from Canada, Mexico and the United States) formally adopted a nearly-identical version as their policy (NAPPO 1994).

- ARS reinstated a *National Program Leader* (NPL) to oversee the Agency's programs on biological control in 1995, a position that had not been filled for several years. In addition, the NPL filling this position has been given the responsibility to enhance inter-agency cooperation, develop biological control action teams in the field, and to conduct targeted workshops to improve technology transfer between ARS research programs and implementation programs of ARS customers and cooperators. Several such inter-agency workshops were conducted over the past year on weed biological control, augmentation biological control, and biological control activities associated with specific commodity programs.

- The International Organization for Biological Control (IOBC), the only global scientific society dedicated to biological control and integrated pest management, adopted a similar statement at their September 1996 General Assembly meeting in Montpellier, France.

Several reports were also published in the mid-1990s which support biological control. A National Academy of Sciences (NAS), National Research Council (NRC) five-year landmark study (NRC 1993) titled *Pesticides in the Diets of Infants and Children* highlighted the danger to children from pesticides. NRC concluded that the pesticides tolerance and regulatory system were lacking and inadequate to protect young children, and residues were permitted that allowed "100-500 times" what is safe for children. Obviously,

increased use of biological control can help reduce pesticide application on crops, thus lowering the risk to children of pesticide exposure.

The OTA report, *Harmful Non-Indigenous Species [NIS] in the United States* (OTA 1993*a*), concluded that there were >4,500 NIS in the United States, of which 15% (>675) cause severe economic or environmental harm. There have been >200 NIS introduced since 1980, and new introductions were increasing. From 1906-91, 79 NIS caused $97 billion direct damage, and OTA concluded that 1991-2000, introduction of just 15 NIS could add $134 billion direct damage. OTA made the critical distinction between accidentally introduced pest NIS, which are the type that cause the enormous damage quoted, and the beneficial NIS, including biological control agents, that should be used more because they help manage the harmful NIS.

The U.S. Congress was so concerned about the situation with pesticides that they charged the OTA to (OTA 1993*b*):

> 1) evaluate to what extent biological pest control can help fill the expected pesticide gap; 2) examine the relative safety of biological pest control and how some of the problems experienced with large-scale use of chemical pesticides, such as pest resistance, can be anticipated and avoided; 3) determine whether the current system of Federal funding, research, incentives and regulations helps or hinders the development and use of biologically-based approaches; 4) address the potential for transfer of biological pest control technologies from agriculture to other pest problems; for example, to weeds on Federal lands, lawn care, household pests, and vector-borne human diseases; and 5) develop policy options for Congress.

The final report (OTA 1995) entitled *Biologically Based Technologies for Pest Control*, was remarkably comprehensive, as discussed above.

Thus, establishment of a national advocacy and philosophical support of biological control has been recommended independently by several groups over an extended period of time. Such a program could help develop educational and informational materials, establish demonstration projects on farms, help coordinate activities and programs, and maintain a "coalition of stakeholders" (Granados *et al.* 1991, Chabot 1991). It could also help to capitalize on the IPM policy initiatives developed independently by a wide variety of groups.

OTA (1995) stated that Congress has responded to the "significance of pesticide losses, pest resistance and emerging pest threats" in several ways in the 1990 *Farm Bill* and subsequent legislation, and notably, by the June 1993 press release by the Clinton Administration, leading to the IPM Initiative.

(4c) Educating customers and stakeholders, leading to an increase in support for biological control.

Charudattan and Browning (1992) stated that State extension agents are key targets for education, who perhaps unknowingly, represent chemical interests through familiarity and training. Growers, who suspect slow-acting technologies, need to understand basic principals of biological control strategies. Regulators, in some cases, are challenged to differentiate a biological control organism from a chemical or similar material. Legislators, who do not know the impact that can be made or even what could be made are "waiting" for a need to act.

Concern was expressed over commercial (generally, augmentative) biological control agents not being predictably reliable, and that the incentives to develop products are insufficient (Glenister 1991, Ridgway *et al.* 1981, Tauber and Helgesen 1981). The private sector often stated that the regulatory system impedes, rather than facilitates, commercial development of biological control agents. There is a lack of ecological information about the fate of commercial biological control agents. Finally, agricultural cosmetic quality standards are thought of as being too high, and unachievable for some products using biological control.

Financial incentives are needed for the commercial sector to increase the supply of biological control agents. It was suggested that incentives for "private good" biological control should include "an 'Orphan Drug Act' for small market biopesticides, research and development tax credits, ... and lowering capital gains taxes to help research and development investments" (Granados *et al.* 1991).

EPA is primarily responsible for regulation of commercial biological control agents (Mendelsohn *et al.* 1993). As a response to customer suggestions, EPA has recently updated their regulatory procedures for approving commercial biological control agents.

Increasing commercialization of biological control remains a global challenge. The private sector can contribute significantly more to this effort if incentives (funding, regulatory and partnerships) are increased.

Concern was expressed over agents not being predictably reliable, and that the incentives to develop products are insufficient. The private sector often stated that the regulatory system impedes, rather than facilitates, commercial development of biological control agents. There is a lack of ecological information about the fate of commercial biological control agents. Finally, the product cosmetic quality standards are thought of as being too high, and unachievable for some products using biological control. NBCI has worked with the private sector, particularly the Association of Natural Bio-Control Producers, on these issues, but much more progress can be made.

Options for Educating Citizens about Biological Control

CSREES, APHIS, State departments, companies and private consultants educate farmers and other citizens about the use of BBTs, according to OTA (1995). However, OTA (1995) stressed that information of use of BBTs is "usually unavailable" to growers, and stressed the need for more activity in this area. OTA identified this as a "significant weak link" in implementation of BBTs, and suggested two options for Congress:

Option. *The Federal Insecticide, Fungicide and Rodenticide Act prohibits the federal government from requiring training in IPM for certification of pesticide applicators. Congress could amend the act to rectify this situation and require that pesticide applicators be knowledgeable in the full range of pest control options, including BBTs.*

Option. *Several different types of consultants affect pesticide use decisions. Several professional associations influence the types of information these consultants provide through training programs and certification standards. Extension has worked with at least one society, the Agronomy Society, to help integrate IPM into their certification program. Congress could encourage similar efforts through the Cooperative Extension System, perhaps by providing targeted competitive funds for projects that involve collaboration between extension personnel and professional societies to integrate BBTs and IPM into training programs or certification standards.*

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APPENDIX 3
WORKSHOP AGENDA

Invitational Workshop on USDA Activities in Biological Control
October 8-11, 1996
Riverdale, Maryland

Session One: Biological Control Coordination in USDA **Tuesday, October 8, 1996**

8:00 a.m. **Introductions and Charge to Participants**
- Welcome and Introductions
  Ray Carruthers (ARS) and Sally McCammon (APHIS)
- Opening Remarks and Charge to Participants
  Larry Elworth, Special Assistant for Pesticide Policy
- Review Workshop Procedures and Norms

9:00 **Panel Presentations on the Roles, Responsibilities and Primary Needs for Biological Control Coordination in USDA**
Moderator: Sally McCammon (APHIS)
Panelists: *Key Agency/Organization Perspectives*
Al Elder (APHIS)
Cindie Fugere (ND Dept. of Agriculture)
Tim Butler (OR Dept. of Agriculture)
Allan Bullard (FS)
Judy St. John (ARS)
Sally Rockey (CSREES)
Dan Mahr (Land Grant University: University of Wisconsin)

9:45-10:00 **Break**

10:00 **Panel Presentations** (continued)

11:15 **Large Group Discussion on Panel Presentations**

12:00-1:00 **Buffet Lunch** - Catered by Harvest Cafe, APHIS Conference Center

1:00 p.m. **Discussion of White Paper Recommendations for Coordination, Cooperation, and Facilitation of Biological Control in USDA**
Discussion Leader: Del Delfosse (APHIS)

1:30 **Review Breakout Group Procedures**
Facilitator: Jane Berkow (APHIS)

1:40-4:30 **Small Group Breakout Sessions on Coordination of Biological Control in USDA**

3:00-3:15 **Groups' Self-Managed Break**

4:30 **Groups Conclude Work, Breakout Group Moderators Meet to Assemble Breakout Groups' Output**

4:30-7:00 **Dinner on your own**

7:00-9:00 **Moderator Group Presents Breakout Groups' Ideas & Facilitates Large-Group Discussion to Identify Components for USDA Biological Control Coordination and Needed Agency Commitments**

Session Two: Biological Control Regulation **Wednesday, October 9, 1996**

8:00-10:30 a.m. **Panel Presentations on the Components of the APHIS Regulatory System for Plant Pests**
Moderator: Allan Bullard (FS)
Panelists:
Sally McCammon (APHIS): *Overview of Strategic Regulations and the ANPR*
Bill Schneider (EPA): *EPA Regulatory Responsibility for Biological Control*
TBA (APHIS): *APHIS Consolidated Statutes*
Carl Bausch (APHIS): *Overview of NEPA Requirements*
Bob Flanders (APHIS): *Current Biological Control Regulatory Procedures*
Andy Rohrer (APHIS): *Voluntary Certification*

10:00 **Large-Group Discussion of the APHIS Regulatory System**

10:30-10:45 **Break**

10:45 **Customer-Identified Needs for Biological Control Regulation: The NBCI-Facilitated "Strawman"**
Discussion Leader: Del Delfosse (APHIS)

11:45 **Large-Group Discussion on the NBCI "Strawman"**

12:00-1:00 **Buffet Lunch** - Catered by Harvest Cafe, APHIS Conference Center

1:00 p.m. **Presentation on Balancing Risks and Regulations**
Jim Cook (ARS)

1:30 **Discussion of White Paper Recommendations for a Regulatory System for Biological Control**
Discussion Leader: David Herron (APHIS)

2:00 **Small Group Breakout Sessions on Regulatory System for Biological Control**

3:00-3:15 **Groups' Self-Managed Break**

5:00 **Groups Conclude Work, Group Moderators Meet to Assemble Breakout Groups' Output**

7:00 **Group Dinner at the Holiday Inn**

Session Two: Biological Control Regulation (*continued*) **Thursday, October 10, 1996**

8:00 a.m. **Moderator Group Presents Breakout Groups' Ideas & Facilitates Large-Group Discussion to Identify Components for USDA Biological Control Regulatory System and Needed Agency Commitments**

Session Three: Accountability of Biological Control in USDA

9:00	**Discussion of White Paper Recommendations to Increase Accountability and to Ensure Feedback from the Scientific Community and Stakeholders** Moderator: Sally Rockey (CSREES)
9:30	**Small Group Breakout Sessions on Accountability of Biological Control in USDA**
10:15-10:30	**Groups' Self-Managed Break**
12:00	**Groups Conclude Work, Group Moderators Meet to Assemble Breakout Groups' Output**
12:00-1:30	**Buffet Lunch** - Catered by Harvest Cafe, APHIS Conference Center
1:30 p.m.	**Moderator Group Presents Breakout Groups' Ideas & Facilitates Large-Group Discussion to Identify Components for USDA Biological Control Accountability and Needed Agency Commitments**
3:00-3:15	**Break**

Session Four: Integration of Output from Sessions 1-3 to Develop Components of a Draft Plan on Coordination and Regulation and Accountability of Biological Control in USDA

3:15	**Moderator Group Facilitates a Large-Group Discussion to Finalize the Whole Group's Recommendations on Draft Plan Components**
6:00	**Dinner on your own.** (Free for the evening.)

Session Five: Presentation of Workshop Results to USDA **Friday, October 11, 1996**

7:00 a.m.	**Participants meet at the College Park Metro Station to leave for Washington, D.C.**
8:00	**Review the Draft Plan Components** Room 107-A JLWFB Discussion Leaders: Sally McCammon and Ray Carruthers
10:00	**Presentation of the Draft Plan Components to USDA Officials** (Deputy Secretary Rominger, Larry Elworth, Floyd Horn, Terry Medley, Bob Robinson, and Jack Ward Thomas) Presenters: Sally McCammon and Ray Carruthers

Proposed Rules

Federal Register
Vol. 61, No. 189
Friday, September 27, 1996

This section of the FEDERAL REGISTER contains notices to the public of the proposed issuance of rules and regulations. The purpose of these notices is to give interested persons an opportunity to participate in the rule making prior to the adoption of the final rules.

DEPARTMENT OF AGRICULTURE

Animal and Plant Health Inspection Service

7 CFR Part 330

[Docket No. 95–095–1]

RIN 0579–AA80

Plant Pest Regulations; Review of Current Provisions

AGENCY: Animal and Plant Health Inspection Service, USDA.

ACTION: Advance notice of proposed rulemaking and notice of public meeting.

SUMMARY: We are soliciting public comment on several issues pertaining to our current regulations regarding the importation and interstate movement of plant pests. Specifically, we are seeking public comment on the criteria used to determine whether an organism is a plant pest; what types of direct and indirect injury or damage to plants and plant products should be regulated; how to facilitate the interstate movement and use of biological control organisms; and how to best evaluate the safety of proposed releases into the environment of organisms with plant pest characteristics. The information gathered through this advance notice of proposed rulemaking will be used by the Animal and Plant Health Inspection Service as we consider the need for regulatory changes and weigh alternative methods of addressing plant pest risk as it pertains to the importation, interstate movement, and release into the environment of plant pest or potential plant pest organisms.

DATES: Consideration will be given only to comments received on or before December 26, 1996. We will also consider comments made at a public hearing to be held on November 7, 1996, from 10 a.m. until 5:00 p.m.

ADDRESSES: Please send an original and three copies of your comments to Docket No. 95–095–1, Regulatory Analysis and Development, PPD, APHIS, Suite 3C03, 4700 River Road Unit 118, Riverdale, MD 20737–1238. Please state that your comments refer to Docket No. 95–095–1. Comments received may be inspected at USDA, room 1141, South Building, 14th Street and Independence Avenue SW., Washington, DC, between 8 a.m. and 4:30 p.m., Monday through Friday, except holidays. Persons wishing to inspect comments are requested to call ahead on (202) 690–2817 to facilitate entry into the comment reading room. The public hearing will be held on November 7, 1996, at the USDA Center at Riverside, 4700 River Road, Riverdale, MD.

FOR FURTHER INFORMATION CONTACT: Dr. Sally McCammon, Science Advisor, OA, APHIS, P.O. Box 96464, Washington, DC 20090–6464, (202) 720–8014, E-mail: smccammon@aphis.usda.gov; or Dr. Robert Flanders, Entomologist, Biological Assessment and Taxonomic Support, PPQ, APHIS, 4700 River Road Unit 133, Riverdale, MD 20737–1236, (301) 734–8896, E-mail: bflanders@aphis.usda.gov.

SUPPLEMENTARY INFORMATION:

Background

The Federal Plant Pest Act (FPPA), as amended (7 U.S.C. 150aa through 150jj), grants the Secretary of Agriculture broad authority to carry out operations or measures to detect, eradicate, suppress, control, or to prevent or retard the spread of plant pests; that authority gives the United States Department of Agriculture (USDA) the flexibility to respond appropriately to a wide range of needs and circumstances to protect American agriculture against foreign plant pests. The FPPA defines a *plant pest* as "any living stage of any insects, mites, nematodes, slugs, snails, protozoa, or other invertebrate animals, bacteria, fungi, other parasitic plants or reproductive parts thereof, viruses, or any organisms similar to or allied with any of the foregoing, or any infectious substances, which can directly or indirectly injure or cause disease or damage in any plants or parts thereof, or any processed, manufactured, or other products of plants."

The Secretary's authority under the FPPA and the Plant Quarantine Act, as amended (7 U.S.C. 151 through 164a, 167) has been delegated to the Administrator of the USDA's Animal and Plant Health Inspection Service (APHIS), which administers regulations and conducts activities for the purpose of controlling and eradicating plant pests. APHIS' Plant Protection and Quarantine program area bears primary responsibility within the agency for those plant pest control and eradication activities.

Many of APHIS regulations in title 7, chapter III, of the Code of Federal Regulations focus on the importation or interstate movement of plants or plant products—e.g., nursery stock, seeds, fruits and vegetables, logs and lumber—as a means of preventing the introduction and dissemination of plant pests that are new to or not widely distributed within and throughout the United States. Those regulations are based on the premise that certain plants or plant products may be a vector of, or be infected or infested with, a plant pest. Similarly, 7 CFR chapter III also contains regulations that restrict or prohibit the movement of articles such as soil, stone, and quarry products, garbage, packing materials, and soil-moving equipment due to the risks that those articles may introduce or disseminate plant pests. Still other regulations in 7 CFR chapter III focus on organisms that may be a vector of, or be infected or infested with, plant pests. Examples of such organisms are live bees other than honeybees of the genus *Apis* regulated under 7 CFR 319.76; live honeybees of the genus *Apis* regulated under 7 CFR part 322; and organisms genetically engineered through recombinant DNA techniques regulated under 7 CFR part 340. Finally, there are regulations that focus on assessing and mitigating the plant pest risks associated with the movement of plant pests themselves.

APHIS' plant pest regulations in 7 CFR 330.200 (referred to below as the plant pest regulations) are for the stated purpose of preventing the dissemination of plant pests into the United States, or interstate, by regulating the movement of plant pests into or through the United States and interstate. When these regulations were first promulgated in 1959, they adequately addressed the needs of the regulated community, which at the time consisted mostly of government and academic researchers. In the years since 1959, however, the range of research and applications involving organisms that present plant pest risk has broadened enormously. In

addition to applications to move the "traditional" plant pests. APHIS now regularly receives requests to import or move interstate organisms such as parasites and predators for the biological control of arthropod pests; centipedes, walking sticks, praying mantises, butterflies, giant cockroaches, etc. for insect zoos; and microbes for soil treatment.

Although the range of organisms for which plant pest permits are requested has changed dramatically since 1959, APHIS' plant pest regulations have not been substantively amended to keep pace with those changes.

Nonindigenous Species Report

APHIS did propose to supplement its plant pest regulations following the September 1993 release of a report by the U.S. Congress' Office of Technology Assessment (OTA) entitled "Harmful Non-Indigenous Species in the United States" (OTA-F-565, Washington, DC: U.S. Government Printing Office, September 1993, referred to below as the OTA report). The OTA report examined pathways through which harmful nonindigenous organisms enter the United States, the harmful effects and economic consequences of many introduced organisms, and the State/Federal regulatory framework in place to prevent their introduction. One conclusion of the OTA report was that Federal agencies, including APHIS, should reevaluate, within their respective areas of responsibility, their approaches to dealing with introductions into the United States of nonindigenous organisms. The OTA report also highlighted the benefits that could accrue as a result of the increased use of biological control in pest management.

In response to the OTA report, APHIS published a proposed rule in the Federal Register on January 26, 1995 (60 FR 5288-5307, Docket No. 93-026-1) to establish new regulations to provide a means of screening certain nonindigenous organisms prior to their introduction to determine the potential plant pest risks associated with their introduction. We received over 250 comments on that proposed rule, none of which supported the proposed rule as written. After considering all the comments, we determined that the revisions needed to reconcile the proposed regulations with the very diverse views expressed in the comments would be so significant that any final rule would be substantially different from the proposed rule on which the public had the opportunity to comment. Therefore, on June 16, 1995, we withdrew the proposed rule (60 FR 31647, Docket No. 93-026-4).

Regulatory Reform

In addition to any issues that may remain unresolved with regard to the recommendations of the OTA report, we have also made a commitment to reassess our plant pest regulations in response to the President's Regulatory Reform Initiative, which, among other things, directs agencies to remove obsolete and unnecessary regulations and to find less burdensome ways to achieve regulatory goals. To further both of those objectives, we have prepared this advance notice of proposed rulemaking to identify and seek input on several issues that we believe must be addressed in order for us to improve the service we provide to our stakeholders and move forward with a long overdue revision of the plant pest regulations. These issues are:

- The criteria used to determine whether an organism is a plant pest;
- What types of direct and indirect injury or damage to plants and plant products should be regulated;
- APHIS' role in facilitating the interstate movement and use of biological control organisms; and
- How to best evaluate the safety of proposed releases into the environment of organisms with plant pest characteristics.

These issues, and our questions regarding them, are discussed in detail below.

Determination of Plant Pest Status

The provisions of the plant pest regulations are most often implemented when a person requests a permit for the importation or interstate movement of an organism that is, or may be, a plant pest or that presents a risk of introducing or disseminating a plant pest. When a person seeks to import such an organism into the United States for the first time, APHIS will generally allow it to enter the country provided the organism is consigned directly to a containment facility inspected by APHIS, particularly if the organism is unidentified or field-collected. Such facilities are designed and operated to minimize the risk that the organisms contained in them could escape. Once in containment, an imported organism is separated from any contaminants (e.g., other organisms or plant materials) and evaluated in terms of the potential it has to directly or indirectly injure or cause damage or disease in plants or plant products. The same evaluation is applied to organisms already present in the United States, i.e. those organisms for which a plant pest permit for interstate movement has been requested.

To determine whether or not an organism is a plant pest or poses a risk of introducing or disseminating a plant pest, APHIS conducts what we refer to as a first-tier pest risk assessment. First, because the identity of an organism is the key to subsequent research, we seek to establish whether the organism has been identified by a recognized authority or, if the species is undescribed or if it belongs to a group poorly understood by taxonomists, whether voucher materials have been deposited in a major U.S. repository, such as the collection at a major university. Once that consideration has been addressed, we then look at the organism in light of five questions; an affirmative answer to any one of these questions would give us reason to believe that the subject organism is a plant pest. Those questions are:

- Does the organism feed on, infect, or parasitize living plant tissues?
- Does the organism feed on, infect, or contaminate plant products such as stored grain, stored fruit, or lumber?
- Does the organism transmit plant pathogens?
- Does the organism develop as a secondary parasite, pathogen, or predator of a primary natural enemy of a herbivore or plant pathogen?
- Does the organism adversely affect commercially important pollinators or important herbivores or plant pathogens that control weeds?

In that those five questions dictate, in large measure, the questions that we would ask on an application for a plant pest permit or in some sort of pre-application guidance document, we would like your comments on those questions. Do they constitute an adequate measure of plant pest risk, or should additional criteria be included?

Indirect Injury or Damage

Many of the commenters who responded to our January 1995 proposed rule were critical of our lack of specificity when it came to what we might consider "indirect" injury or damage to plants or plant products. The tone of the proposed rule implied that we considered potential injury very broadly to include all negative impacts of all organisms within food chains where plants are the primary producers. Under such a scheme, herbivores and plant pathogens cause direct plant injury, while parasites and predators at higher trophic levels may cause indirect injury; any proposed insertion of an organism into a food web would require an evaluation of all potential disturbances within that food web.

While some groups may support an approach that requires an evaluation of all potential significant environmental impacts of introducing new organisms into an established food web, other groups strongly oppose that approach because it means that many parasites, predators, and pathogens that have traditionally been released to control herbivores and plant pathogens (i.e., biological control organisms) would be defined as plant pests because their effects on their intended targets could be construed as causing indirect injury or damage to plants or plant products.

In order that we may more clearly delineate the types of effects that could be considered "indirect" injury or damage to a plant or plant product and thus bring a greater degree of clarity or predictability to the plant pest permitting process, we are offering the following interpretation of "indirect" injury or damage for your consideration:

Direct and indirect injury or damage refers only to impacts within a food chain that negatively affect plants or plant products. Thus, for example, parasites or predators that inflict population-level damage on herbivorous invertebrates would not themselves be considered plant pests because their actions cause a reduction in direct injury or damage to plants or plant products. However, organisms at the next higher trophic level (e.g., hyperparasites) would be seen as causing indirect injury or damage to plants or plant products if they suppress the actions of the parasites, predators, or pathogens that would otherwise reduce the degree of direct injury or damage to plants or plant products. Similarly, because organisms such as honey bees, bumblebees, etc. are critical pollinators, any parasites, predators, or pathogens that adversely impact those pollinators would be seen as causing indirect injury or damage to plants or plant products due to the potential negative impact of reduced pollination.

Considering all the ramifications, is this interpretation of indirect injury or damage too narrow, or would a broader interpretation of indirect injury or damage unnecessarily hinder or delay the resolution of plant pest problems?

Voluntary Standards

When, as a result of our review, we determine that an organism is not a plant pest, we will inform the applicant that a plant pest permit is not required for the importation or interstate movement of the organism. In many cases, an applicant will request that APHIS issue a courtesy permit for the movement of such an organism. The plant pest regulations provide for the issuance of courtesy permits for the movement of organisms that are not subject to regulation under the FPPA or any other act, as a courtesy to facilitate movement when the movement might otherwise be impeded because of the similarity of the organisms with others regulated under the FPPA. Such permits are most frequently requested for the interstate movement of parasites, predators, and pathogens that are intended for use in the biological control of plant pests.

APHIS deals regularly with State plant health officials who wish to see some Federal regulatory oversight for the interstate movement of such organisms. That is one of the reasons that courtesy permits are so often issued to facilitate the interstate movement of parasites, predators, and pathogens that are intended for use in the biological control of plant pests. Indeed, it may be desirable for there to be some degree of regulatory oversight on the part of APHIS to address the plant pest risks related to the movement of field-collected biological control organisms and host material.

One idea that has been raised that might fill any potential regulatory void while promoting the use of biological control is the formation of a cooperative program involving Federal and State agencies, biological control producers and distributors, and the biological control research community. The goal of the cooperative program would be to establish and promote compliance with a set of voluntary or consensus standards for the interstate movement and release into the environment of organisms used in the biological control of plant pests.

Under the FPPA, the Secretary of Agriculture is authorized to carry out measures to prevent or retard the spread of plant pests, either independently or in cooperation with States, farmers' associations and similar organizations, or individuals. In that the voluntary program would be a cooperative effort to facilitate research into and the movement of organisms used to prevent or retard the spread of plant pests, we believe that it could be established under our existing statutory authority.

A benefit of the plan would be that it could serve as a "seal of approval" for biological control researchers, producers, and distributors in the sense that its guidelines would be considered optimal for the research community and the industry. The voluntary plan could be operated under standards produced through consensus by its participants, i.e., government, industry, and the research community; a document drafted and widely distributed by the National Biological Control Institute, a non-regulatory unit within APHIS, entitled "Options for Changes in Biological Control Regulations and Guidelines in the United States: A Strawman for Comment" is one example of the form that the voluntary plan's guidelines could take. Because participation in the plan would be voluntary, individuals would be likely to participate in the program as long as the benefits they derive from the program outweigh any added costs they might incur through their participation.

Would the level of support and participation from industry and the research community be great enough to justify the formation of such a program?

We are interested in receiving any ideas at all about the membership, leadership, responsibilities, funding, authority, etc. of a voluntary, cooperative program for organisms intended for the biological control of plant pests.

Releasing Plant Pests

When we have reason to believe that an organism is a plant pest or poses the risk of introducing or disseminating plant pests, that organism will be held in containment or refused permission to be moved interstate. However, there are organisms that possess plant pest characteristics but that have potential applications outside the laboratory or containment that would recommend their eventual release into the environment. Specifically, such organisms may have use in the biological control of weeds.

APHIS would only consider allowing such an organism to be released into the environment after it has been determined that the organism causes population-level injury, damage, or disease in a demonstrably narrow range of closely related plant species. The targeted plant species must also be overwhelmingly considered undesirable weeds before APHIS would consider allowing the release of an organism displaying plant pest characteristics.

We believe that a case can be made for the considered release into the environment of certain organisms that manifest plant pest characteristics; indeed, APHIS has, on a case-by-case basis, considered and granted approval for such releases. However, our current plant pest regulations make no provisions for such releases.

The demonstrated benefits accruing from the public and private use of integrated pest management principles make it likely that the use of organisms for the biological control of weeds will only increase. Therefore, we believe that it is necessary to develop standards that

would allow us to determine whether an organism could be safely employed for the biological control of weeds. Through our previous experience with determining the safety of potential biological control organisms of weeds, we have developed several questions that speak to the primary factor that must be considered in assessing such releases, i.e., host specificity. Those questions are:

- Does the organism feed upon, infect, or suppress only the target plant species or a few closely related species?
- If an arthropod, does the organism deposit eggs on plant species besides the target? If so, how closely are these plant species related to the target? Similarly, if the organism is a plant pathogen, can its spores or other propagules germinate and penetrate the tissues of plants other than the target?
- If the organism deposits eggs on plant species other than the target, do those eggs hatch and can the resulting immature stages significantly feed on them and complete their development? For plant pathogens, does penetration of the plant tissues lead to disease symptoms or signs in the plant?
- If the organism is an arthropod, are its immature stages capable of completing development on plants other than the target, and are the resulting adults fertile? Similarly, if the organism is a plant pathogen, does infection of nontarget plants result in the subsequent production of viable spores or other infective units?
- Does the probable ecological range (especially those related to tolerances for physical environmental parameters, especially temperature and humidity) of the organism overlap the distribution of native plant species that are related to the target in the United States and that are attacked in laboratory tests?
- Is the organism closely related to other species or strains that exhibit narrow or broad host specificities?
- Can the organism feed upon, attack, infect, or otherwise adversely impact endangered or threatened plant or animal species in the United States?

We are seeking your input on the appropriateness of these questions for assessing the risks of releasing organisms with plant pest characteristics for the biological control of weeds. What other considerations might be appropriate for such an assessment? Should any special requirements be imposed on organisms proposed for release on islands such as Puerto Rico or the State of Hawaii? Should APHIS require applicants to submit post-release monitoring data regarding possible attacks on nontarget plant species?

Public Hearing

APHIS will host a public hearing to provide interested persons a full opportunity to present oral presentations of data, views, arguments, and questions regarding this advance notice of proposed rulemaking. The hearing will be held on November 7, 1996, at the USDA Center at Riverside, 4700 River Road, Riverdale, MD.

A representative of APHIS will preside at the public hearing. Any interested person may appear and be heard in person, by attorney, or by other representative. Persons who wish to speak at the public hearing will be asked to sign in, listing their names and organizations.

The public hearing will begin at 10 a.m. local time and is scheduled to end at 5 p.m. local time. However, the hearing may be terminated at any time after it begins if all persons desiring to speak have been heard. We ask that anyone who reads a statement provide two copies to the presiding officer at the hearing. If the number of speakers at the hearing warrants it, the presiding officer may limit the time for each presentation so that everyone wishing to speak has the opportunity.

We welcome all comments on the scope, approach, criteria, and issues outlined above and encourage the submission of ideas on any associated topics or other suggestions for the evaluation of plant pest risk and the improvement of the evaluation and permitting process. APHIS will consider all comments and recommendations in developing any revisions to the current FPPA regulations and will initiate rulemaking for any changes deemed appropriate.

Authority: 7 U.S.C. 149, 150bb, 150dd, 150ee, 150ff, 154, 159, 160, 162, and 2260; 21 U.S.C. 136 and 136a; 31 U.S.C. 9701; 7 CFR 2.22, 2.80, and 371.2(c).

Done in Washington, DC, this 24th day of September 1996.

Terry L. Medley,

Administrator, Animal and Plant Health Inspection Service.

[FR Doc. 96-24847 Filed 9-26-96; 8:45 am]

BILLING CODE 3410-34-P

INVITATIONAL WORKSHOP ON USDA ACTIVITIES IN BIOLOGICAL CONTROL

Breakout-Group Moderators

	Session I: Coordination	Session II: Regulation	Session III: Accountability	Group Name	Location
A	Yokomi	King	Carruthers	Phytophages	(Conference Center, Left-Front)
B	Barnes	McFadden	Gould	Parasites	(Conference Center, Right Front)
C	Delfosse	McCammon	Quimby	Predators	(Conference Center, Left Back)
D	Rockey	Wendel	Huettel	Antagonists	(Conference Center, Right Back)
E	Bullard	Center	Coulson	Competitors	(Rm 2D02)
F	Hopper	Cook	Leppla	Nematodes	(Rm 3B01)
G	Heron	Oraze	Knutson	Pathogens	(Rm 6B01CN)

Alphabetical List of Attendees and Breakout-Group Assignments

Attendee	Session 1: Coordination	Session 2: Regulation	Session 3: Accountability
Robert Balaam, NJ (SDA)	C	F	E
John Barnes, Washington, DC (CSREES)	B	E	F
Stan Barras, Washington, DC (FS)	D	F	D
Carl Bausch, Riverdale, MD (APHIS)	A	C	G
Larry Bezark, CA (SDA)	D	G	D
Allan Bullard, Morgantown, WV (FS)	E	G	C
Tim Butler, OR (SDA)	E	G	C
Ray Carruthers, Beltsville, MD (ARS)	G	D	A
Ted Center, Ft. Lauderdale, FL (ARS)	A	E	G
Raghavan Charudattan, University of Florida, Gainesville, FL (CSREES)	C	F	E
Pat Cimino, Washington, DC (EPA)	C	F	E
James Cook, Pullman, WA (ARS)	B	F	F
Jack Coulson, Beltsville, MD (ARS)	C	E	E
Gary DeBarr, Athens, GA (FS)	F	G	B
Ernest Delfosse, Riverdale, MD (APHIS)	C	A	E
Jack DeLoach, Temple, TX (ARS)	D	C	D
Donald Eggen, DE (SDA)	F	A	B
Al Elder, Washington, DC (APHIS)	B	A	F
Robert Faust, Beltsville, MD (ARS)	E	F	C
Bob Flanders, Riverdale, MD (APHIS)	D	C	D
Arnold Foudin, Riverdale, MD (APHIS)	E	B	C
Cindie Fugere, ND (SDA)	G	B	A
Bill Gimpel, MD (SDA)	A	C	G
Julie Gould, Phoenix, AZ (APHIS)	C	A	B
Deb Hayes, Washington, DC (FS)	G	A	A
Ron Hennessey, Riverdale, MD (APHIS)	F	B	B

Dave Heron, Riverdale, MD (APHIS)	G	D	A
Keith Hopper, Newark, DE (ARS)	F	C	B
Robin Huettel, Raleigh, NC (CSREES)	D	F	D
Dennis Isaacson, OR (SDA)	B	C	F
Barry Jacobson, Washington, DC (CSREES)	E	G	C
Ed King, Weslaco, TX (ARS)	G	A	A
Deborah Knott, Riverdale, MD (APHIS)	A	D	G
Alan Knutson, Texas A&M University, Dallas, TX (CSREES)	F	G	B
Lloyd Knutson, Montpellier, France (ARS)	A	A	G
Dennis Kopp, Washington, DC (CSREES)	G	A	A
Tim Kring, University of Arkansas, Fayetteville, AR (CSREES)	A	C	G
Daniel Kucera, Radnor, PA (FS)	A	A	G
Norm Leppla, Riverdale, MD (APHIS)	B	E	F
Mike Lidsky, Riverdale, MD (APHIS)	C	E	E
Barbara Madden, Beltsville, MD (ARS)	B	G	F
Dan Mahr, University of Wisconsin, Madison, WI (CSREES)	B	A	F
George Markin, Bozeman, MT (FS)	B	C	F
Sally McCammon, Washington, DC (APHIS)	D	C	D
Max McFadden, Radnor, PA (FS)	C	B	E
Michael McManus, Hamden, CT (FS)	D	B	D
Bill Metterhouse, NJ (retired) (SDA)	C	C	E
Dale Meyerdirk, Riverdale, MD (APHIS)	E	F	C
Michael Montgomery, Hamden, CT (FS)	E	D	C
Barbara Mullin, MT (SDA)	D	D	D
Karl Narang, Beltsville, MD (ARS)	C	G	E
Bob Nowierski, Montana State University, Bozeman, MT (CSREES)	C	B	E
John Obrycki, Iowa State University, Ames, IA (CSREES)	G	B	D
Dennis O'Dowd, HI (FS)	F	D	B
James Olivarez, Missoula, MT (FS)	G	E	A
Steve O'Neil, Riverdale, MD (APHIS)	F	F	B
Michael Oraze, Riverdale, MD (APHIS)	G	G	A
Richard Parry, Beltsville, MD (ARS)	D	B	D
Janet Petroff, Bozeman, MT (ARS)	D	A	G
Ronald Phillips, Washington, DC (CSREES)	E	D	C
Dave Prokrym, Niles, MI (APHIS)	A	G	G
Chuck Quimby, Sidney, MT (ARS)	E	B	C
Richard Reardon, Morgantown, WV (FS)	A	E	G
Bob Riley, Washington, DC (CSREES)	F	D	B
Sally Rockey, Washington, DC (CSREES)	D	E	A
Mike Rose, Bozeman, MT (CSREES)	A	C	G
Bill Schneider, Washington, DC (EPA)	B	E	F
Tom Sim, KS (SDA)	E	E	C
Bhisham Singh, Beltsville, MD (APHIS)	B	A	F
James Slavicek, OH (FS)	B	F	F
Judy St. John, Beltsville, MD (ARS)	F	D	B
Ralph Stoaks, Sacramento, CA (APHIS)	D	B	D
Nancy Sweeney, Riverdale, MD (APHIS)	E	B	C
Jim Vaughn, Beltsville, MD (ARS)	G	D	A
Robert Waltz, ID (SDA)	F	F	B
Lloyd Wendel, Mission, TX (APHIS)	F	D	E
Lyle Wong, HI (SDA)	G	G	A
Ray Yokomi, Orlando, FL (ARS)	A	E	G

These notes are copied from flipchart pages compiled by each breakout group. The notes are reproduced exactly as written , although the obvious abbreviations are written in full.
Numbers refer to worksheet question numbers.
(?) = handwriting unclear.

SESSION I: COORDINATION DISCUSSION
Tuesday, Oct. 8, 1996

GROUP C

1 - Goals:
- To deliver programs.
- Micro- and macro-coordination.
- Best use of funds/increase $.
- Define national-regional-local roles.
- NPR context: Reinvention lab.
- Reduce bureaucracy/overhead.
- *Increase communication* - advocacy.
- *Prioritizing targets* and research needs / implem. needs.
- Long-term funding / strategic vs. action.
- Congress: No-year $ for biological control or delineated year.
- White House interest.
- Pool $ from USDA agencies for coordination.
- >$ to CSREES for biological control.
- Use CAPS for priorities / funding.
- Better science, monitoring-feedback.
- Need sunset clause - outcome/success.
- Need organized structure to coordinate.
- Need political coordination for >$, national policy and legislation
- Grants for private industry (NSF, SBIC)
- Documentation and importation, release, etc.
- International: North America and outside North America.

2 - What areas should be coordinated?
- Implementation: regional, state, national
- Target prioritization
- Research - forum to ensure balance (e.g., pathogens)
- Foreign exploration
- Quarantine
- Lobbying (private & public) / Education / Information
- Regulation
- Communication
- Funding/solicitation, allocation
- Environmental issues
- ANBP - Tech transfer, sm. grants
- Policy / advocacy
- Customer input to projects (incl. field scientists)
- Needs for taxonomic research and IDs - R.A.
- Review, evaluation (continue or end project)

3 - Coordination needs...
- National interagency coordination committee (has authority / policy)
- Customer advisory groups (wide membership)

DS ← structure ← APHIS-ARS-CSREES-FS = NICC
↑ stakeholder input (CG: NPB, states, DoI, DoD, etc.)

Deputy Secretary
|
authority/accountability → NBCI (transfer from APHIS)
↘ |
(? cord. cmts) APHIS-ARS-CSREES-FS-(BCDC?) - 1-2 positions from each agency
↑
Customer advisory group

4 - Barriers
- Agency turf
- Resources, including $
- Political: state vs. state, region vs. region (NPB, NASDA, NAPPO - supportive)
- Sociopolitical: Congress, activists, environ.
- Many mandates, that are not supported, funding not (?) mandate
- No philosophical support
- Perceptions (?) < cost:effectiveness
- Chemical industry ("silver bullet" mindset)
- Narrow definition of BC/BBT/BBPM/ERPM/(?BtNPM)
- Perceptions of NT impact: lack of education
- Possible legal challenges
- Trade barrier?

Opportunities
- Build on existing coord. @ field level
- State BCCC
- IPM mandate (75% by 2000)
- Alleviate public concern about food safety
- Increase revenue to growers
- Innovative ways to generate resources (herbicide tax, junk vehicle, drivers license tax)
- Small enterprises: niche markets
- Involve (?Th?) groups (SBA)
- Decrease cost to public / public benefit
- Decrease production costs?
- Better science, (?..nper-hund..), strategic
- Political bandwagon
- See "Goals" - opposite of Barriers

5 - Components
- Infrastructure (staff, resources, secy-authority, accountability)
- (?) to get 1^2
- Measureable goals / outcomes
- Role identification for implementation, research, foreign exploration, etc.
- Buy-in, consensus-building
- Charter for the infrastructure
- Team-based
- Publicity of successes / information / education

GROUP D

1 - Coordination goals for USDA BC cooperation:
1. What are we coordinating? Focus/definition?
2. Who's responsible in each agency? What is the role of each agency in BC?
3. Parasites/predators/pathogens
   Establish roles of agencies
   1. Why: stakeholders know
   2. Make sure bases covered / no duplication
4. Who do stakeholders go to?

5. Practical program easy to understand / up and running (Who go to? Coordinating body? Policy / availability)
6. What level? (state, multi-state, accountability)
7. Varies depending on program

ARS ➔ APHIS ➔ states -- could be other ways

Strategies for agreeing upon pests/priority
- Coordinate at state/regional/national?
- How can USDA facilitate at state level?
- Canvas at local level (bottom-up; local puts up 90% of $)

Coordination at federal level should facilitate bottom-up
- Forest Service research plan model moves up/not down
- APHIS-PPQ: 3-5-yr plan
- CSREES: PIG grants, piecemeal

Washington cut red tape - Need one-stop shopping
- NBCI model for info
- Council - USDA
- Model: Big pest programs of the past - had $ - Above agency level

Selection of projects at grassroots ➔ feasibility study - state, BoR, Audubon

Next steps to implement:
- Grassroots ➔ constituents ➔ $
- Feds ➔ $
- Feds: point of contact; build budget based on local needs; research

Targets: identify needs (universities, ARS)

Stragetic plan to coordinate with the states
- Buy-in by agencies
- Budget cycle (leverage federal $, 3-5 states/problem)

Coordination of agency roles
- Roles now changing
- Avoid duplication
- What are we working on?

2 - What coordinated?

1. Research - domestic and overseas? Databases on foreign exploration.
2. Feasibility studies indicate what's already done
   - Availability of info
   - Responsibility of each agency for particular resources - how to access database

Coordination = access to information
- Field level good; upper levels bad; database resolves

Who is last word in each agency?
- Multiple disciplines/projects
- Information flow/access/resource

CSREES - Russian wheat aphid - model

Education and communication with customers - successes

Coordination and know how priority-setting for research projects

Regional pot - from different agencies - open competition - build consortia at grassroots.

Agencies/personnel - need to know where fit into system

Overseas: facilitate information flow

Council - (?Ceorce) Body

Develop - Implement (not coordinate, but *bridge* from research to implementation - NBCI)

Exotic weeds APHIS / Ag crops ARS

Researchers work with implementers
- Researchers need continuity, partnership, info people at state level, *communication*

Regulations
- Need appropriate input from scientists
- Sunset - formalizing
- Access to FR - or other ways to distribute, scientific societies
- Input to development
- Review

Evaluation
Coordiantion with EPA/F&WS/states
Risk statutes are adequate

3 - Coordination needs / potential for delivery:
Area information "officer"
Continuity of research ➔ implementation ➔ education

4 - Barriers
Reward system in agency / universities
Authority for funds (research, Extension, other)
Disconnect agency-administration-(?obpa) - passback; Will be problem if "grassroots priorities"
Turf wars
Project duplication
OTA report - $ (symantics on reporting)

Opportunities
Budget reflect coordinated program
Biocontrol Symposia on regular basis

5 - If federal biocontrol coordination is to facilitate local and regional biocontrol needs, what should federal strategic plan look like?
Assess/coordinate (how?) local and regional needs - all affected agencies.
Match needs with current agency roles and mission. Identify gaps/duplication.
Develop Dept. strategic plan.
Identify how agencies identify needs
What models are effective? (Go to "key" people; flexible.)
Are there gaps?
Focus role expectations of USDA
How is USDA going to evaluate itself in coordinating biocontrol?
Reduce duplication
Strategic plan
Milestones
Stakeholder/customer evaluation (NBCI form)

GROUP E

1 - Goals for coordinating
Formal or informal? Biocontrol coordinated framework.

Why coordinate?
Best use of resources (technical, scientific, fiscal)
Avoid conflict between agencies
Achieve efficiency (with resources - do more with less; avoid overlap)
Coordination (can possibly inhibit creativity protecting turf)
Facilitation
Communication - very important; figure out who's doing what, who can help
Facilitate team players and teamwork
Identification and prioritization as a team effort
Helps avoid problem with public perception (public buy-in)

Goal: Central leader (maybe NBCI upgrade) to Department level governed by a board of directors (agency buy-in); mission beyond USDA - operational.

Goal: Identify roles of each agency in biocontrol (identify overlap, linkage to develop).
Request for Team Biocontrol: Provide a list from each cooperator of:
1) Who is working on BC?
2) Where are they located?
3) What are they working on?
4) Where are all of the quarantine facilities located, including states, FS, ARS, APHIS, etc.?

2 - Areas to be coordinated:
Classical biological control

Coordination of foreign explorations (lots of groups to help)
Coordinate importation through cooperators
Coordination of quarantine facilities
Permit processes, esp. with development of EAs
Need to develop a plan to more actively include out-of-agency groups
Coordinate mass production
Coordinate evaluation of establishment, short- and long-term impact, economics
(Who has this role? Define roles.)
Coordinate technology transfer through Extension, DOAs, universities
Biological control implementation
Perception of production agriculture
Social science used to sell
Regulations
Avoid overlapping requirements (NEPA, Coastal Zone Mgmt, T&E, EPA, FDA)
State regulations
Coordination with other countries
Education of reviewers of programs
Coordinate with sister technologies: medical technologies, IPM approaches
Develop a marketing plan
Successful programs
Sell the technology to identified groups (avoid oversell)
Augmentative biological control
IPM approach compatibility/testing
3 - huh?? Needs (3 tiers):
1. Central leadership
Elevate NBCI to a higher (Dept) level with a multi-agency/multi-department board of directors
Define agency responsibilities
Let interested cooperators know what they are
2. Develop a Council at the Secretary level
Someone who can make decisions
Supply policy guidance
3. Technical coordinating teams (maybe project or focus area)
Working group
Report to Council
States to identify BC specialist from each state, i.e., coordinate themselves
(ESCOP? working group on biocontrol)
4 - Barriers and Opportunities
Communication
Turf
Funding / resources
Pool resources - development of weed-specific consortia
Unwillingness to share credit
Lack of a central focus within USDA - scattered groups. Develop one central administration.
Time is right to develop better coordination (fewer funds, IPM initiative)
Develop and maintain a central database
Use shared inventories (satellite, remote sensing, etc.)
New regulations being developed (we can mold them to fit biocontrol)
Public sector in competition with private sector
Administration discussing privatization
Development of CRADAs with a private company (more applicable to augmentative BC)
Secrecy of the patent process; better review for the public good.
5 - Components:
Priority setting
Planning
Broad-based regional input on priorities

Technology transfer
Needs of 1) action agencies within USDA, and 2) other agencies
Economics
Environmental aspects
Practicality of the target (probability of success)
Identify targets using a biocontrol matrix
Endangered pesticide uses (lack of alternative controls)
Look down the road for where there are control gaps
Benefit:Risk analysis
Develop a "bad guys" list to watch out for, develop a plan to deal with them.
Good idea that an organism may become a problem pest
Who is responsible for priority setting? The Council, based on technical committee recommendation.

GROUP F

1 - Why coordinate?
- Funding limits ➔ more efficient use of resources
- Delineate responsibilities
- Divison of labor
- Economy of scales, e.g., share quarantine
- Develop consensus, goals
- Increased funding- attracts other sources
- Reduced risk of litigation
- Better communication with stakeholders (esp. Congress)
- Less complex, more coherent, smoother regulatory process
- Reduced regulatory botlenecks through better communication, education
- Stimulating intellectual synergism
  - Greater efficacy
  - Improved morale
- Greater opportunity
- Stability of programs
- Better checks and balances

2 - Areas to coordinate:
- Research: of course!
  - Prioritization, basic knowledge, regulatory issues, target pests (amenable to BC, economic impact, environmental impact)
  - Current prioritizaton mechanisms inadequate
- Need to coordinate everything!

3 - Needs & Delivery, i.e., how to coordinate:
- Allocation of resources (people, money, facilities)
- Coordination at all levels, especially at field level

3,5 - How to coordinate?
- How to prioritize targets?
  - Research
  - Implementation
  - Model: APHIS/ARS/CSREES prior. of rangeland weeds
- How to resolve lack of consensus?
  - Framework for cooperation/coordination/collaboration
  - Need small (<16) representative committee - representatives from heads of agencies ➔ support by undersecretary and agency heads; reps from scientists expert on subject; input from user groups.
- How chosen?
  - Four agency reps appointed by heads of agencies
  - Four scientist reps (spectrum of disciplines within BC: plant pathology, insect pathology, BC of weeds with insects, BC of insects with arthropods) - nominated by peers, appointed by administrators.

Tour of duty: 2-3 years, staggered.
Work/year: 2 meetings/yr, 1-2-day meetings, first day meet with users in workshop, second day closed committee.
Product: Collaborative plan for biological control.
Secretary/facilitator to hold (? relsros, proude) committee.

GROUP G

1 - Coordination goals:
- To get product for the money spent.
- To accelerate progress toward solutions.
- Avoid duplication.
- State and Federal governments are the only ones in position to coordinate.
- Create efficient programs for inception to implementation.
- To make the best use of our dwindling resources.
- To know who is doing what! (i.e., research, implementation, tech transfer)
- To facilitate reaching a goal.
- To define the problems (prioritize) so that resources can be used to achieve solutions.
- Identify the resource base (personnel, funds, facilities, locations, stakeholders/users).
- To share information amongst collaborators.
- To build trust and strengthen relationships.
- To acquire a commitment toward a functional technology. (i.e., biocontrol)
- To harmonize biological control activities.

2 - Coordinate what areas?
- All areas need to be coordianted into a comprehensive, systematic approach.
- The systematic approach should include, but not be limited to: initiation/conception, research, development, funding, regulation, tech transfer, implementation, education, monitoring, evaluation, follow-up.

3 - Coordination needs:
- An interagency body with adequate authority to implement a systematic approach (not limited to statutory authority)
- Users need to beincluded in the systematic approach and making the decisions.
- Examine and build incentive systems for the scientific community involved in this technology.
- Open communication among all the parties.
- Establish procedures that are agreed upon by all to develop operational plans.
- Clearinghouse of information accessible to all.
- To develop Departmentwide policies and goals. Strategic plan.
- Inventory past efforts and delivery systems that work. Peer review funding system. e.g., consortiums, action plans, mandated education systems
- Training like EPA/PAT (Extension agents and state and private forestry)
- Education through elementary and secondary and university
- Fee-for-service biocontrol activities (check off)

4 - Barriers and opportunities
- Maintain enough flexibility for creativity.
- Barrier: Agencies protecting their authority and resource base (job security).
- Barrier: Institutional cultures
  - Incentive systems
  - Decision-making processes
  - Lines of authority
  - Different philosophies
  - Different constituencies
  - Different seat of authority (centralized vs. decentralized)
- Barrier: Difficulty is accessing economic impacts of pests in different environments (cropland, rangeland, natural areas)
- Barrier: Difficulty in communicating relative impacts.
- Barrier: Lack of adequate communication.

Barrier: Politics driving funding.
Barrier: x/o funding for implementation program (IBC[3], NRI, biocontrol grants)
Opportunities:
- Plenty of room for improvement.
- Resources are in place, but need to be reallocated.
- Opportunity to show that government can successfully implement a desirable technology.
- Biocontrol is in line with changing cultural philosophies (and executive directives, too).

5 - Coordination system components:
Look to private sector for successful models.
Dedicated positions to biological control coordination.
Involvement with user advisory panels, commodity boards, etc.
Unifying document that states policy and goals. (Everyone agrees to this document.)
Mechanism to focus on bioregional approach (defined by biology, not by political borders).
Clearinghouse for information (Documentation Center)
Funds specifically earmarked for cooperative or collaborative efforts.
Fact book for decision-makers.
Producted-oriented *now*!
Education of users, general public, other agencies.
Continuity - figure out what works and stick with it for awhile (programs, personnel, regulations and funding).
Short-term goals.
Long-term goals.

GROUP (A or B, no letter recorded)

1 - Goals:
To become more efficient in the development/implementation of biological control.
To anticipate/identify issues early in the R&D process (questions likely to be raised by different action/reg. federal/state; questions likely to be raised by scientists/environmentalists).
To maximize successes in biological control.
Set priorities for funding.

2 - What areas to coordinate:
Share data on safety across state/federal/other country (Coord. regulatory; multiple statutes).
Research development education (coordinate the science)
Communication / education
Increase transparency as to "what's ahead"
Generic system that works/applies across naturally occurring ➔ Gen. mod.
International cooperation (minimize duplication; IPR)

3 - What are coordination needs?
Incentive(s) to coordinate
Money for R&D
Prospects for increased scrutiny/expectations
Socioeconomics

4 - Barriers
Line-item budgets and turf
Politicized budget process
Opportunities
CSREES regional research projects and coordinating committee
Time is right.
New technologies
Commercialization potential

5 - Components of USDA system:
Mechanism for setting priorities

Economic
Social
Environmental
Probability of success
Transferability
Bench-marking
Success stories
Protocols appropriate to the strategy / need
Peer review for scientific standards
Stakeholder input
Regulations appropriate to the risk

GROUP (A or B, no letter recorded)

1 - Goals:
Planning / education
Publicizing and defining successes
Funding (focusing resources, stability/continuity of programs)
Agencies prioritize and intereact
Minimize duplication
Ability to be flexible
Mutual goal-setting/planning
Synergy benefits of dealing with all clients
Linking grassroots with upper management

2 - What should be coordinated?
Regulatory consensus
Concrete action steps
Funding
Customer input (lobbying, $)
Authority (to assign funding)
Maintaining base funds
Creative funding
Redirection
Coordinate all biocontrol areas
Add public relations, technology transfer
Support overseas exploration
Tax. support, quarantine
Implementation - define
Production, release, redistribution.
Regional 3-5 states - larger efforts may be problematic

3, 4 - Barriers
Territory
Lack of continuity (upper-level management, programs)
Funding
Unrealistic timeframe for implementation
Communications
Education
Regulation
Complexity of biocontrol

Opportunities
Joint leadership
USDA-wide commitment
Multi-year funding
Effective planning and communication
Communications
Education
Regulation

Research and novel ways to package biocontrol

5 - Components
- Interagency council / mechanism
- Feedback from end-user
- Problems and needs statement
- Assessment of capabilities
- Economic analysis
- Evaluation system
- Conflict of interest resolution

SESSION II: REGULATION DISCUSSION
Wednesday, Oct. 9, 1996

GROUP A

1. - Expedite BC programs by:
   - Resolve conflicts of interest
     a. Preserve natural environment
     b. Preserve safety of agricultural systems
   - in process of facilitating importation and in long-term and short-term effects
   - Document introductions/releases/establishments (important to precedence)
   - Expeditious movement of BC organisms
     - Customer-friendly process (discover-research-transfer-quarantine-research-release-establishment-evaluation)
     - Maintenance of high safety record of BC
     - Assure public and agricultural community of credibility of process and safety of organisms
     - Scientifically based, logical process
     - Facilitate availability and distribution
2. Consistent with risk
   - Identification of risk - how?
   - Risk assessment
   - Extent of assessment
   - * Identification of risk and benefit consistent with extent of problem
   - Oct. 8-9-10: Quality Control Session
3. Strawman: Adopted unanimously and funded
   - Interagency Coordinating Body
   - TAG for weeds - strengthened and formalized
   - TAG for entomophagous BC agents?
4. - Barriers:
   - Turf - fear of loss of authority (perception or real)
   - Status quo
   - Fear of lawsuits/liability/making a mistake
   - Negative public perception
   - Lack of vocal support

   Opportunities:
   - Increasing success in establishment
   - Committed partnership of BC community
   - Gain greater public recognition and support for BC paradigm
   - Increase customer service
   - White hat
   - Interest of high-level policy-makers

GROUP B

What needs to be included in a regulatory system?

- Consistent system of peer and stakeholder review for the entire process of regulating system.
- Philosophy and policies of regulatory system must be clearly stated.
- Need to move toward the facilitative model (incl. conflict resolution).
- Transparent (user guides, Web sites, electronic permitting)
- Mandatory turnaround times (60-90 days)
- User advisory panel
- Information delivery system (minimum standards and guidelines, databases, notifications, precedented organisms' EAs and EISs, sample forms and applications.)
- Integration of states into the process.
- Keep TAG and put their findings/recommendations on the Web.
- USDA Department-level NEPA coordination
- NEPA documentation choices (regulators write or scientists write)
- Straightforward and clear protocol for review and clearance of non-indigenous pathogens (plant and animal)
- Separate out the biological control of weeds immediately and facilitate it as a necessary technology.
- We support development of stand-alone regulations for all biological control under FPPA.
- Tailor regulatory approach to target organisms.

Goals to regulate biocontrol in USDA:

- Release of safe organisms - fast!
- Facilitate biological control
- Enhance trade
- Enhance human health
- Reduce farmers' costs
- Reduce negative impact of pesticides
- Balance regulations with risks
- Reduce infestation of exotic weeds and insect pests
- Gain public trust
- Foster public support
- United we stand, divided we fall = USDA
- Stop the fractioned political approach to biological control.

3a. - First time introductions:

- Host plants range or specificity
- Identification
- Place of origin
- Evidence
- Bionomic information

3b. Refer to Strawman

3c. Explore who will lead the conflict resolution process (maybe TAG)

3d. The ability to "contain organisms" in quarantine until biosafety is proven and pose no threat to the environment

- Adopt SOPs
- Level of quarantine needs to fit target organisms.

GROUP C

1. Regulate only to the extent necessary.
   Avoid introduction of damaging organisms, but allow beneficials.
   Intro, movement, release domestic & exotic organisms.
   * Facilitate timely implementation of BC
     a. Plant pest regulations
     b. NEPA requirements
     c. Etc. - T&E - state
     d. CSREES/ARS/APHIS/FS work together (EPA?)

Understandable projects will promote regional and state support.
Have a process that targets pests and 3 or 4 general insects
programmatic EIS
general look
classify stuff
identify appropriate organisms
Programmatic EIS
ANPR info for BC
Structure environmental regulation associated with FPPA regs
Should NEPA be part of voluntary certification?

Goals:

Clear regulatory authority for plant pests, especially re: release issues. Unclear for non-plant pests (specialists less controversial; generalists)
Coordinated framework for NEPA
Consolidation for regulatory compliance for environmental regs
Point of focus
Streamlining of regulation requirements/systems
Recommend APHIS response. (EAD/PPD not BATS)
Specificity testing
Should it be a requirement?
Non-plant feeding < 10% - first-time release
APHIS develop options for dealing with non-plant pests
Other acts/regs
Deal with environmental issues
Systematically look at exemptions/exclusions (under NEPA?)

2. - Level of regulation

Begin process of BC law
Want protection
Into consolidated statutes - BC protection
Level commensurate with risk
Policy - BC safe (demonstrate the safe and useful)
Biologically based - truism (will be competition for resources)
Identify truisms with scientific community on BC - environmental issues (NEPA doc for BC; programmatic EIS for BC)

3. Precedented status defined (EA/T&E, established, indigenous, naturally occurring, exclude from regulatory process precedented, indigenous); deal with the past, develop for the future.

Strawman is a good starting point
- 1/3 in process already; 1/3 not relevent; 1/3 looking at
- Strawman gives good recommendations (researchers, addresses issues, TAG, look at seriously)

4. - Barriers

Coordination
Clarification of processes
Communication
Timeliness
New form (526) movement for non-plant feeder (Plant Board, ANPR)

Opportunities

State laws / interaction / coordination
NEPA = B & O
Gain credibility / publicity

GROUP E

1. - Goals for regulation:

Environmental protection/acceptance
Protect discipline - enable BC to proceed

Protect human/animal health
Bring order to process from research to implementation to application (regulatory certainty)
Protect agriculture
Satisy legal requirements
Avoid pitfalls

2a. - What level, given the risks?
s/b proportional to risk
Minimal needed
Flexibility/adaptive
Tiered: "routine" or "high risk"

2b. - What administration level s/b involved in regulation? (USDA)
At Departmental level (NEPA compliance office, permitting, risk assessment, endangered species, etc.)
Regulatory clearinghouse/one-stop shopping for guidance/info (opportunity to help states without BC expertise)
Liaison: interdepartmental (EPA, DoI)
Models: Global Climate Change, NAPIAP, Aquaculture, IPM

3. - What to be included?
Importations:
Quarantine certification (matched to agents imported)
Lacey Act, CITES (notification of F&WS and foreign country permits)
APHIS notification
Integration of permitting process & quarantine certification
Timely recertification of quarantine facilities
Voucher specimens
Involvement of APHIS in quarantine construction, design, planning
Precedented introductions (too simplistic in White Paper):
Sunset provison in permits
Taxonomic verification
Disease elimination
Streamline commercial production
Heed state regulation
Changing T&E issues
Changing taxonomy
Working toward self-regulation within industry, but not ready yet
Categorical exclusions for certain groups of organisms (e.g., *Encarsia*)? If so, how does it affect EPA jurisdiction? Needs careful consideration!
First-time introductions:
Most of above also applies
Courtesy permit - what next? Allow movement / not release
APHIS could establish risk acceptance database. Are we regulating weed BC agents because we can? How about 2500+ immigrant species that can't regulate? Pest exclusion big field, BC small part!
What about pests of animals?
What about plant pest potential of plant introductions? Double standard: BC agent guilty til proven innocent, plant intro. innocent til proven guilty.
Realistic host-screening expectations to expedite new agents: guidelines needed: scientific vs. political rationale
Conflict resolution:
Systematic process badly needed prior to final decision to allow release
Resolution at lowest possible level (e.g., TAG member to scientist)
Advocacy role of departmental (regulatory) clearinghouse - NBCI?
Regulations need well-defined appeal process
Public hearings?
TAG action posted on Internet
Make system transparent for public

4. - Barriers & Opportunities
Clear definition of official departmental spokespersons for TAG member agencies
Use permitting process for easy decisions, ad hoc system for difficult. Lack of process thinking!
Computerized tracking/decision-making system could be developed (e.g., Lotus Notes)
Difficulty getting "scientists" to take regulatory jobs. Need to make more attractive.
Different groups reticent to give up "control."
Improved standards for quarantine testing might be helpful.
Improve customer service - add resources to enable/empower this. Get voice mail!

GROUP G

1 - Goals for regulating BC
FIFRA exemption based on regulation by other agency - if no, then EPA
Confidence of public
EPA might be more rigorous in data needs
Protect U.S. agriculture/environment
USDA responsibility
States depend on Federal oversight
Consistency of regulation
Biocontrol community develop regs rather than someone else
Mechanism for more BC
Roadmap/path for compliance with regulations - more efficiency
Clear regulation will provide basis for commercialization/research
Clear regulatory structure will make for fewer ad hoc decisions; allow predictability in decisions

2 - More plants T&E than insects/animals
Level of regulation of BC, given risks
Level of regulation based on science, NOT public perception
What are the levels of risk?
High (phytophagous, vectors, generalist > specific, predator > parasite, T&E species)
Low (unprecedented > precedented, high birth rate > low birth rate, high mobility > low mobility, displacement of native organisms - reduced biodiversity)
HOT STUFF: * USDA Environmental Documentation Unit - clearinghouse, one-stop shop (in APHIS?)
At present time, level of regulation is not issue - laws in existence
- Clarity and pathway is important
- NEPA, etc.
- Regulatory compliance coordinated across USDA, between agencies

3 - Needs
Harmonization in North America (possibly through NAPPO)
TAG for entomophagous BC agents, at appropriate level
Streamlined, responsive, common sense, sensible, "minimum" regulations, science-based
Incorporate current risk analysis concepts
Include benefits statements
Positive proofs based on data
Regulate quarantine
Process for conflict resolution
Ad hoc, peer-review, conflict resolution team option for serious problems, one that allows appeal

4 - Barriers:
Turf - internal and external
Funding
Communication
Lack of clear guidelines
Lack of leadership
Lack of authority

Continuity between agencies
Regulations too complex

Opportunities:
Create comprehensive protocol; systematic approach putting regulatory issues up front.
(?) Regulate voucher species for unnatural species
Clearinghouse for environmental info/documentation
Current momentum and "critical mass"
High-level support
Opportunity to address a growing concern
Opportunity to streamline regulations
Time is right!!

GROUP (D or F, no letter recorded)

1 a and b - Why regulate?
If USDA doesn't, someone else will
To assure the public; to safeguard public interests; to foster public support
To protect American agriculture, forestry, and ecosystem
To provide a mechanism for public/peer review and conflict resolution
To facilitate commercialization

2 - Level of regulation (degree of regulation):
Proportional to the level of risk vs. benefit
At a minimum to do the job
One coordinated EA/EIS format across agencies

3a - Information needed:
Taxonomy
Host/ecological range
Life cycle/general biology
Should go into containment/quarantine if the BCA is a "plant pest"

3b - Notification with documentation of the precedence and state concurrence

3c - Arbitration process that is science-driven

3d - Current inspection and approval containment requirements adequate

3e - Expect the unexpected
A regulatory roadmap
A review system for unprecedented cases (not agents)

4 - Barriers:
Turf
Fiscal and human resources
Lack of fundamental information
Politics and indecision

Opportunities:
Implementation of this workshop recommendations

GROUP (D or F, no letter recorded)

1. - Goal: To facilitate the evaluation and use of safe & effective biological control agents while excluding organisms that maybe do harm to the environment.

2. - Level of regulation
Regulation balanced with risk
Multiple tiered system
Benefits must be considered (i.e., J.Cook - against other technology being developed, BC vs. chemical technology)
NEPA considerations - more than one agency involved
Benefits vs. not using BC technology
Containment
Authority for regulation of BC agents [Currently, phytophagous - APHIS; entomophagous - other agency making release; no regulation within states (-) fed $'s]

A single group with regulatory authority of BC agents is needed.
Enabling legislation to provide this authority (Farm Bill). This should be written into Research Title of the Farm Bill - 1998.

3. - Regulatory systems
    - First-time introductions
        - Risk
        - Non-target screening - all
        - Level of containment
        - Ecological & physiological
        - Post-release monitoring & evaluation based on level of risk
        - Pre-release information on native spp. or other BC agents released. NEPA concerns.
        - Exclusions based on previous successful releases
        - Published/current guidelines for introductions
    - Precedented BC agents and interstate movement
        - Maintain exclusion list based on they have been previously released unless some new discovery of impacts or conflicts since earlier release
        - Reviewed routinely for changes
        - Regional implications, i.e., Hawaii -
    - Interstate movement
        - State concern - some regulatory, others notification is OK
        - Other than Hawaii
        - No 526 involved unless requested by individual states
    - Conflict resolution
        - Mediation is first option.
        - Formal process - with timelines
    - Quarantine and laboratories
        - Where are they, what are needs for more?
        - Utilization - increase
        - Finalize & publish guidelines (keep current)
        - Post-permit report on 526 (feedback of permit use process) - networked with Documentation Center; ... monitoring
    - Issues:
        - Entire regulatory process needs to be addressed holistically (remove fragmentation)
        - Cooperatively develop dynamic, coherent, documented regulatory process using existing BATS process and "Strawman"
        - Clarify indirect plant injury issue and how it affects regulatory process
        - Initial draft of regulations should be made available internally in USDA.
        - Initial draft of regulations should address internal USDA customers first, then adjusted for external customers (Fed. agencies, SDA)

4. - Barriers
    - Perception of obstruction
    - Unclear regulation
    - Lack of authority
    - Turf
    - Expensive
    - Unclear jurisdiction
  - Opportunities
    - Cooperative state/federal initiative
    - Increased public support
    - Increased public confidence in no environmental harm
    - Increased and supporting awareness at Department level
    - Enhanced economic support for farmers and land managers
    - Last workshop!

SESSION III: ACCOUNTABILITY DISCUSSION
Thursday, Oct. 10, 1996

(Note: A number of participants were unable to attend the entire workshop. Some Session III breakout groups were combined to facilitate a broad discussion.)

GROUP (no letter recorded)

1 - To whom are USDA biological control programs accountable?
- Agency
- Congress
- Congress
- Stakeholders
- Taxpayers/public
- Partners/cooperators
- Scientific community

2 - For what are we accountable?
- Control of pests by biological means
- Safety, in compliance with regulations (a. food supply; b. environment)
- Cost-effective use of resources
- Quality performance / good science
- Communications / education
- Technology transfer
- Prioritization of agriculture problem-solving
- Team approach
- Meeting changing needs

3 - How to measure accountability:
- a. Involve economists and environmentalists and sociologists
- b. Specific quantitative performance measurements, e.g.,
  - No. of BC agents researched/*released*
  - No. of targets
  - No. of crops affected (acres)
  - No. of states involved
  - No. of farmers, industry using technology
  - No. of publications - scientific & technical
- c. Qualitative performance measurements
  - Degree of acceptance of technology
  - Interagency involvement
- d. Fiscal measurements, e.g., grants
- e. Outcomes/bottom line
  - Scientific outcomes (No. of successful controls)
  - Economic outcomes

GROUP (no letter recorded)
- Accountability could and should occur.
- What is the return of public investment in biocontrol?
- What is the safety record for biocontrol?
- What is being done to solve specific problems?
- Continuous feedback
  - Database (1-importations, 2-organisms released, 3-establishment, 4-evaluation of impact, 5-funds spent)
  - Make info available to the public / administrators
- Accountable to whom?
  - General public
  - Special interest groups (i.e., grower groups, environmental groups)
  - USDA agencies

State Departments of Ag
Scientific peers
Agency needs to be held accountable to finish the job until the pest is controlled.
Educate Congress what is involved in that task.
Provide updates (Congress, special interest groups) of progress and pest status and if problem still exists (needs more work)
Effective ways
Database (Documentation Center)
Coordinating body provide info to Congress/special interest groups; get info from database
Each agency has its own accountability system; improve, reconcile, coordinate among agencies:
- ARS and CSREES - CRIS/RMIS - accounting system, funding
- FS - RBAIS
- APHIS - specific projects

GROUP (no letter recorded)

Regulatory Accountability
All accountability measures should be quantifiable.
Timely permitting process.
Apply GPRA principles
Efficiency
Withstands legal challenges
Policy-level people make policy; implementation-level carries it out.
High success rate for conflict resolution
Knowledge-based policy-making
Written and recorded policies
Base pest management systems on natural/biological controls
Consistent decisions
Document the use of biocontrol in IPM

Research Accountability
Apply GPRA principles
Biocontrol community develop a code of ethics
Use a program logic model that extends from inputs to outputs and outcomes
Outcomes in the field (# organisms developed)
Documented scientific breakthroughs
Program evaluation = customer satisfaction
Peer review
Adoption by users
Mission orientation
Timely publication for public domain

Delivery accountability
Apply GPRA principles
Helps to solve the problem
releases in the field
Environmentally friendly
acres treated and controlled
New commercial products
Decrease pests
Decrease in pesticide use
emerging businesses
Measurable qualitative and quantitative products
No adverse environmental effects
Healthier ecosystems
Increased trade
Increased or more efficient agricultural production and profitability
Number of producers/land managers that use biological control systems

GROUP (no letter recorded)

Accountability of whom by whom??
- U.S. citizens, Congress, Secretary of Agriculture
- Policy - need a strategic plan - $ resources, $ authority, goals/objectives/expected outcomes; measures - defined for individuals/agencies; outputs
- Policy-makers
- [Coordination]
- Research
  - Resources for biological control?
  - $ given to agencies - relative to PLAN
  - More management of $ for biological control?
    - Reduced flexibility at lab area
    - Line item for particular projects
  - Accountability at regions?
    - Labs running multiple projects outside biological control
    - Flexibility of funds at regional level
    - Single-year funding
- Delivery
- Biological control carry-over funds - because of nature of biological control
  - Monies may be tied to salaries (not easily moved)
  - APHIS funding for base budget (to operate labs)
  - Designated biocontrol monies should not be used for lab overhead
  - Monies should not go to the regions
    - Greater accountability with a Center
    - Cost of maintaining a group of biocontrol practitioners, with APHIS
- Increase TAG groups?
  - Project selection
  - Clearinghouse for new projects
  - Documentation Center
- Feedback system
  - e.g., gypsy moth biological control
  - Regional committees - local input from states - up to Center - for priority projects
  - Local problems need to be addressed
- Who evaluates projects?
  - Prioritization of targets - done at a higher level
  - Project selection
  - Process - across agency lines [Caution: over-management, over-control]
  - Each agency may function autonomously
- Need for interagency cooperation
- Examples of problem-solving across agencies
- Common need
- Enviromental groups support biological control - must be involved - customers
- Caution - good people, good system
- Accountability ➔ Feedback & Involvement ➔ Accountability
- What have you done??
- Project selection / termination process
- State notification
- Programmatic EIS - tier environmental assessments (form of accountability)
- Congress - earmark biological control funds
- Strategic plan➔coordination➔prioritize projects➔[need strong leadership]➔strategic plan